

# **EXHIBIT B**

Jimmy W. Mays, Ph.D.

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC  
REPAIR SYSTEM PRODUCTS  
LIABILITY LITIGATION

Master File No.

2:12-MD-02327

MDL NO. 2327

THIS DOCUMENT RELATES TO THE  
FOLLOWING CASES IN WAVE 1 OF MDL  
200:

JOSEPH R. GOODWIN  
US DISTRICT JUDGE

Bonnie Blake, et al., v. Ethicon,  
Inc., et al.,  
Civil Action No. 2:12-cv-00995

Robin Bridges v. Ethicon, Inc.,  
et al.,  
Civil Action No. 2:12-cv-00651

Carey Beth Cole, et al., v.  
Ethicon, Inc., et al.,  
Civil Action No. 2:12-cv-00483

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MARCH 2, 2016

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Deposition of JIMMY W. MAYS, PhD, held at  
Marco Island Marriott Beach Resort, South Collier  
Boulevard, Marco Island, Florida, commencing  
at 8:36 a.m., on the above date, before Joan L.  
Pitt, Registered Merit Reporter, Certified  
Realtime Reporter, and Florida Professional  
Reporter.

- - -

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1	Angela Coleman, et al., v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-01267	1 APPEARANCES: 2 DOUGLAS C. MONSOUR, ESQUIRE Monsour Law Firm 3 404 North Green Street Longview, Texas 75601 4 903.758.5757 doug@monsourlawfirm.com 5 Representing Plaintiffs 6 JIM M. PERDUE JR., ESQUIRE Perdue and Kidd 7 510 Bering Drive, Suite 500 Houston, Texas 77057 8 713.520.2500 jperduejr@perdueandkidd.com 9 Representing Plaintiffs
2	Dina Destefano-Raston, et al., v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-01169	10 CHAD R. HUTCHINSON, ESQUIRE Butler Snow LLP 11 1020 Highland Colony Parkway, Suite 1400 Ridgeland, Mississippi 39157 12 601.985.4401 chad.hutchinson@butlersnow.com 13 Representing Defendants
3	Dennis W. Dixon re: Estate of Virginia M. Dixon, Deceased v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-01081	14
4	Karyn E. Drake, et al., v. Ethicon, Inc., et al., Civil Action No. 2:12-cv-00747	15
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<p>1           ---</p> <p>2         THE COURT REPORTER: Raise your right hand, 3         please. Do you swear or affirm the testimony you 4         give will be the truth, the whole truth, and nothing 5         but the truth?</p> <p>6         THE WITNESS: Yes.</p> <p>7         THE COURT REPORTER: Thank you.</p> <p>8         JIMMY W. MAYS, PhD, called as a witness by the 9         Defendants, having been first duly sworn, testified 10       as follows:</p> <p>11            <b>DIRECT EXAMINATION</b></p> <p>12         BY MR. HUTCHINSON:</p> <p>13         Q. Good morning.</p> <p>14         A. Good morning.</p> <p>15         Q. My name is Chad Hutchinson. I'm counsel for 16         Ethicon and Johnson &amp; Johnson.</p> <p>17         Dr. Mays, you understand you're under oath?</p> <p>18         A. I do.</p> <p>19         Q. And do you understand you're giving testimony 20         subject to the penalty of perjury?</p> <p>21         A. Yes.</p> <p>22         (Mays Exhibit No. 1 was marked for 23         identification.)</p> <p>24</p>	<p>1         Q. When you say it's not everything you've seen, 2         what do you mean by that?</p> <p>3         A. Well, I've got a whole electronic file of 4         documents that I've gone through.</p> <p>5         Q. Why did you choose to bring the documents in 6         Exhibit 2 today rather than the documents that you have 7         on the electronic file?</p> <p>8         A. I thought those were the most relevant to the 9         matter at hand.</p> <p>10        Q. Okay. I see 49 hours on the invoice. Does 11        that represent the total amount of time that you've 12        spent on the Ethicon litigation?</p> <p>13        A. No, that was as of the time I submitted that 14        bill, which I think was late December or maybe early 15        January.</p> <p>16        Q. Okay. And so up until the time when you were 17        first retained, up until January 4, 2016, you spent 49.5 18        hours; correct?</p> <p>19        A. Correct.</p> <p>20        Q. All right. And since January 4, 2016, up until 21        today, March 2, how many hours have you spent?</p> <p>22        A. Probably about 20.</p> <p>23        Q. So that's approximately 70 hours total that 24        you've spent?</p>
<p>1         BY MR. HUTCHINSON:</p> <p>2         Q. I've handed you what's been marked as Exhibit 1 3         to your deposition. Have you seen that document before?</p> <p>4         A. Yes.</p> <p>5         Q. And that's a notice of deposition; correct?</p> <p>6         A. Correct.</p> <p>7         Q. And that notice lists all the cases in which 8         you're designated as an expert witness in this -- in 9         this litigation; correct?</p> <p>10        A. As far as I know, yes.</p> <p>11        Q. And you brought with you some documents today?</p> <p>12        A. I did.</p> <p>13        Q. And you're handing those documents to me. It's 14        a file approximately 2 inches thick in a manila folder. 15        We'll mark it as Exhibit 2 to your deposition.</p> <p>16         (Mays Exhibit No. 2 was marked for 17         identification.)</p> <p>18         BY MR. HUTCHINSON:</p> <p>19         Q. What does this include?</p> <p>20         A. It's got the bill that I've submitted thus far 21         in this case and also the papers and documents that I've 22         reviewed in preparing for the depo today; not everything 23         I've seen, but everything I basically reviewed for 24         today.</p>	<p>1         A. Yes.</p> <p>2         Q. Thank you. And do you still charge \$300 an 3         hour for review and \$500 an hour for testimony?</p> <p>4         A. Correct.</p> <p>5         Q. Doctor, you've been an expert witness before; 6         is that correct?</p> <p>7         A. Yes.</p> <p>8         Q. And you've been deposed at least twice as an 9         expert against Boston Scientific?</p> <p>10        A. Yes.</p> <p>11        Q. And you read those transcripts?</p> <p>12        A. Yes. It's been a while, but I've read them.</p> <p>13        Q. And you stand by the testimony that you've 14        given?</p> <p>15        A. I do.</p> <p>16        Q. What's your area of expertise?</p> <p>17        A. I'm a polymer scientist.</p> <p>18        Q. Do you have a specialty as a polymer scientist?</p> <p>19        A. Well, I've been involved with polymers broadly. 20        I've worked in the industry for a while. I've been at 21        the university since 1988. I've got an affiliation with 22        Oak Ridge National Lab. So I've worked broadly in the 23        area of polymer science, including polypropylene.</p> <p>24        Q. Do you have a specialty, sir?</p>

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<p>1 A. I would say my specialty is two things, polymer 2 synthesis and polymer characterization.</p> <p>3 Q. You don't have a specialty in organic coatings, 4 do you?</p> <p>5 A. No.</p> <p>6 Q. Doctor, all the work that you've done in mesh 7 litigation has been for the plaintiffs; is that correct?</p> <p>8 A. Yes.</p> <p>9 Q. And you've been retained to offer opinions 10 against Boston Scientific?</p> <p>11 A. Yes.</p> <p>12 Q. And Ethicon?</p> <p>13 A. Yes.</p> <p>14 Q. What about AMS?</p> <p>15 A. No.</p> <p>16 Q. Bard?</p> <p>17 A. No.</p> <p>18 Q. Any other mesh manufacturers?</p> <p>19 A. No.</p> <p>20 Q. Any other polypropylene manufacturers?</p> <p>21 A. Actually, I have been involved with litigation 22 involving polyolefins, including polypropylene, at one 23 point in time, but this was years ago.</p> <p>24 Q. Was that a patent matter?</p>	<p>1 Q. In what matters?</p> <p>2 A. It was the same thing, Boston Scientific.</p> <p>3 (Mays Exhibit No. 3 was marked for 4 identification.)</p> <p>5 BY MR. HUTCHINSON:</p> <p>6 Q. Doctor, I'll hand you what we'll mark as 7 Exhibit 3 to your deposition. That's a copy of your 8 expert report; correct?</p> <p>9 A. Yes.</p> <p>10 Q. And is it complete?</p> <p>11 A. That's what I'm looking at. It looks to be complete.</p> <p>12 Q. Is it accurate?</p> <p>13 A. Yes.</p> <p>14 Q. Are you aware of any errors?</p> <p>15 A. I caught a couple of typos, but they were just, you know, nonconsequential-type things.</p> <p>16 Q. Doctor, how many hours did you spend preparing that report?</p> <p>17 A. I could go back and review my bill and tell you exactly, but it was something of the order of probably 30 hours actually preparing the report.</p> <p>18 Q. Okay. So if we look at that bill that has 49 hours, that would be 30 hours preparing your report and</p>
<p>1 A. It was a patent matter.</p> <p>2 Q. When were you first contacted in this Ethicon 3 mesh litigation?</p> <p>4 A. In this litigation, it was sometime in the fall 5 of last year.</p> <p>6 Q. The fall of 2015?</p> <p>7 A. Yes.</p> <p>8 Q. And who contacted you?</p> <p>9 A. I think it was Mr. Perdue initially.</p> <p>10 Q. And what were you asked to do?</p> <p>11 A. I was basically asked if I might be available 12 to work with them on this matter.</p> <p>13 Q. And what did you tell them?</p> <p>14 A. I said, "Yeah, I think I have time and can do 15 it."</p> <p>16 Q. Did you ask any questions about the scope of 17 the engagement?</p> <p>18 A. I really didn't, as I recall.</p> <p>19 Q. Have you ever worked with Mr. Perdue before?</p> <p>20 A. We worked together in the Boston Scientific 21 matter.</p> <p>22 Q. What about Mr. Monsour? Have you ever worked 23 with him before?</p> <p>24 A. Yes.</p>	<p>1 19 hours reviewing documents and literature; correct?</p> <p>2 A. Roughly that, yeah.</p> <p>3 Q. Okay. Thank you. Did you draft that report, sir?</p> <p>4 A. I did.</p> <p>5 Q. Did you have any assistance in drafting that report?</p> <p>6 A. No, I pecked it out with two fingers on my -- 9 on my laptop.</p> <p>10 Q. Did anybody have access to that document, sir, 11 during the drafting stage?</p> <p>12 A. I did send it at the point when it was a full 13 draft, with references included, at that point I did 14 send it to the attorneys to have a look.</p> <p>15 Q. Okay. But that expert report is your work and 16 your work only; correct?</p> <p>17 A. Correct.</p> <p>18 Q. And does that report contain all the opinions 19 that you intend to offer in this case?</p> <p>20 A. Well, I can't say that with absolute certainty. It might depend on what you ask me, but the gist of what 21 I plan to testify about is in this report.</p> <p>22 Q. Okay. But when you began preparing that report, did you intend to include all the opinions that</p>
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<p>1 you intend to assert against Ethicon and Johnson &amp;      2 Johnson in this litigation?</p> <p>3 A. That was my intent, yes.</p> <p>4 Q. Doctor, did you review or rely on any documents      5 or literature other than what's contained in your      6 reliance list?</p> <p>7 A. As I mentioned, I certainly read a lot of      8 literature in preparing for this. I've worked in the      9 area of polypropylene for years, and things I've been      10 exposed to 30 years ago, I still rely on some of that      11 knowledge. Right? But basically what I relied on is in      12 the references listed at the end of this report.</p> <p>13 Q. A copy of your CV is included within that      14 report; correct?</p> <p>15 A. Correct.</p> <p>16 Q. And is that the most recent version of your CV?</p> <p>17 A. It changes often as new papers are published      18 and new presentations are made. Let me take a look at      19 it and I can tell you how up-to-date it is.</p> <p>20 This one is about a month old, so it's quite      21 up-to-date, but not perfect.</p> <p>22 Q. What would make it perfect?</p> <p>23 A. A couple of additional papers that were      24 submitted at the time have been accepted, and maybe one</p>	<p>1 MR. MONSOUR: Objection. Form. Would you just      2 state those out for me?</p> <p>3 Q. Stress urinary incontinence or pelvic organ      4 prolapse.</p> <p>5 A. No.</p> <p>6 Q. Doctor, have you ever published any articles on      7 Prolene?</p> <p>8 A. I can't say with certainty that I haven't,      9 because I've been in the game a while. I worked for      10 Hercules, one of the largest polypropylene producers in      11 the world at that time, for five years, but I don't      12 explicitly recall anything.</p> <p>13 Q. Okay. And my question is specifically about      14 Prolene.</p> <p>15 A. I understand.</p> <p>16 Q. Okay. Doctor, have you ever given any      17 presentations regarding Prolene?</p> <p>18 A. Again I'll say the same thing I just said      19 regarding the publication. I've been in the area a long      20 time, I've worked with polypropylene before, but I don't      21 recall anything explicitly with Prolene.</p> <p>22 Q. Thank you. Doctor, is all your research      23 experience included on your CV?</p> <p>24 A. Yes, I think it's a good representation of my</p>
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<p>1 additional paper that's been submitted for publication.</p> <p>2 Q. What papers?</p> <p>3 A. Again, I'd have to go back and look.</p> <p>4 Q. Do the papers have anything to do with      5 polypropylene?</p> <p>6 A. They don't.</p> <p>7 Q. Anything to do with pelvic mesh?</p> <p>8 A. No.</p> <p>9 Q. Doctor, are you currently working on any      10 articles that you intend to submit for publication?</p> <p>11 A. Yes. I'm continually working on articles that      12 I plan to submit for publication.</p> <p>13 Q. Do they have anything to do with Prolene?</p> <p>14 A. No.</p> <p>15 Q. Pelvic mesh?</p> <p>16 A. No.</p> <p>17 Q. Doctor, Imel was the first publication where      18 you discussed pelvic mesh products; correct?</p> <p>19 A. Correct.</p> <p>20 Q. And you didn't do the hands-on testing on those      21 explants referenced in the Imel paper, did you?</p> <p>22 A. I did not.</p> <p>23 Q. Have you ever published anything regarding SUI      24 or POP?</p>	<p>1 research experience.</p> <p>2 Q. Have you ever done any research regarding      3 Prolene?</p> <p>4 A. You mean laboratory experiments?</p> <p>5 Q. Yes, sir.</p> <p>6 A. No laboratory experiments. Literature      7 research, yes.</p> <p>8 Q. And, Doctor, since 2014 when you were deposed      9 in the Boston Scientific litigation, have you ever      10 worked with a medical device company specifically      11 regarding pelvic mesh products?</p> <p>12 A. I'm sorry. Could you repeat that?</p> <p>13 Q. Sure. Since 2014, have you ever worked with a      14 medical device company regarding pelvic mesh products?</p> <p>15 A. No.</p> <p>16 Q. And, Doctor, before litigation against Boston      17 Scientific, had the focus of your research interests      18 been on pelvic mesh?</p> <p>19 A. No.</p> <p>20 Q. Doctor, have you ever talked with any of the      21 plaintiffs in this litigation?</p> <p>22 A. No.</p> <p>23 Q. Have you ever talked with any of the      24 plaintiffs' family members or friends in this</p>

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<p>1 litigation?</p> <p>2 A. Not to my knowledge.</p> <p>3 Q. What about any of the doctors?</p> <p>4 A. No.</p> <p>5 Q. Other than attorneys, have you discussed your 6 opinions with anyone else?</p> <p>7 A. No.</p> <p>8 Q. None of your colleagues?</p> <p>9 A. No.</p> <p>10 Q. Any type of scientific organization?</p> <p>11 A. No.</p> <p>12 Q. Doctor, did you sign a confidentiality 13 agreement with respect to the documents you reviewed for 14 Ethicon?</p> <p>15 A. Yes.</p> <p>16 Q. Where is that?</p> <p>17 A. I don't know.</p> <p>18 Q. Would it be at your house, or your office, 19 rather?</p> <p>20 A. It probably would be in my office in Knoxville.</p> <p>21 Q. Do you advertise your services?</p> <p>22 A. I do not.</p> <p>23 Q. Would the time sheet that we have in the 24 collective Exhibit No. 2 reflect all the time that you</p>	<p>1 Q. Are you an expert in female anatomy?</p> <p>2 A. No.</p> <p>3 Q. Doctor, based on your review of the documents, 4 you'll agree that Ethicon performed biocompatibility 5 testing on its Prolene?</p> <p>6 A. Yes.</p> <p>7 Q. And do you have any opinions whatsoever 8 regarding the biocompatibility testing of Prolene?</p> <p>9 A. I've already said I'm not an expert in 10 biocompatibility, but it seemed to be standard-type 11 biocompatibility testing.</p> <p>12 Q. And based upon your review, do you believe that 13 Ethicon appropriately did its biocompatibility testing?</p> <p>14 A. I -- as far as I can tell, they did. What they 15 didn't do that I think they should have done is actually 16 performed clinical trials with the material in the 17 application in which it was intended.</p> <p>18 Q. Doctor, have you ever designed or participated 19 in a clinical trial regarding mesh?</p> <p>20 A. Not regarding mesh.</p> <p>21 Q. Have you ever designed or participated in any 22 type of clinical trial regarding Prolene?</p> <p>23 A. No.</p> <p>24 Q. Have you ever been involved in any clinical</p>
<p>1 spent in this litigation for Ethicon?</p> <p>2 A. This reflects the time I spent in this 3 litigation as of January 4 of this year.</p> <p>4 Q. All right. Thank you.</p> <p>5 Doctor, do you anticipate doing any additional 6 work or research in this Ethicon litigation?</p> <p>7 A. I'm not sure.</p> <p>8 Q. You don't have any plans to, sitting right 9 here, sitting here today?</p> <p>10 A. Not as I sit here.</p> <p>11 Q. Have you asked counsel for any information or 12 documents that you've not received yet that you believe 13 may be helpful?</p> <p>14 A. No.</p> <p>15 Q. I believe it's your testimony you're not an 16 expert in biomaterials?</p> <p>17 A. Well, I have worked in the area of 18 biomaterials. I have considerable expertise in 19 polymeric biomaterials.</p> <p>20 Q. You are holding yourself out as an expert in 21 biomaterials; is that correct?</p> <p>22 A. Yes.</p> <p>23 Q. Are you an expert in biocompatibility?</p> <p>24 A. No.</p>	<p>1 research regarding mesh?</p> <p>2 A. No.</p> <p>3 Q. Have you ever received any grants for studying 4 mesh in your positions at UT or UAB?</p> <p>5 A. No.</p> <p>6 Q. Have you ever designed pelvic mesh?</p> <p>7 A. No.</p> <p>8 Q. And you've never done any biomechanical testing 9 of pelvic mesh; correct?</p> <p>10 A. Correct.</p> <p>11 Q. Have you ever personally inspected a mesh 12 explant of any kind?</p> <p>13 A. Yes.</p> <p>14 Q. Would that be for the 11 explants in the Boston 15 Scientific litigation?</p> <p>16 A. Yes.</p> <p>17 Q. Anything else?</p> <p>18 A. Concerning polypropylene mesh?</p> <p>19 Q. Correct.</p> <p>20 A. I've certainly looked at literature that 21 describes it.</p> <p>22 Q. I'm talking about actually inspecting an actual 23 explant specimen.</p> <p>24 A. No, not other than those Boston Scientific</p>

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1 materials. 2 Q. And you've never personally inspected a mesh 3 explant of Prolene, have you? 4 A. No. 5 Q. Have you ever done any testing of a mesh 6 explant of Prolene? 7 A. Not of Prolene. 8 Q. And, Doctor, are you -- do you know what 9 medical products you're here and designated to testify 10 about and give opinions about? 11 A. Yes, I do. They're listed at the beginning of 12 my report. 13 Q. Where do you see that? 14 A. If you go over on page 4, under background, the 15 various Prolene mesh products are listed there. 16 Q. Sir, do you know if all those products -- and 17 just for the record, we're looking at Prolene Mesh, 18 Gynemesh PS, Prolift, Prolift +M, Prosima, TVT-Secur -- 19 I'm sorry -- Gynecare TVT System, TVT Retropubic, TVT-O 20 TVT-Abbrevo, TTVT-Secur, and TTVT-Exact; is that correct? 21 A. I'm sorry. Could you -- 22 Q. Is that the list of the medical -- 23 A. That is the list, yes. 24 Q. And, Doctor, do you know if all those products	1 Q. Doctor, what about TTVT-Secur, the mesh in 2 TTVT-Secur? Strike that. 3 Prosima. Doctor, do you know what other 4 materials other than Prolene are in the mesh material in 5 Prosima? 6 A. Not as I sit here. 7 Q. Doctor, have you ever seen -- and when I say 8 "these medical devices," just so you and I are 9 communicating, I'm talking about the medical devices 10 that you're here to give testimony about. Are we 11 communicating? 12 A. Yes, sir. 13 Q. Okay. Doctor, have you ever seen these medical 14 devices? 15 A. No. 16 Q. Have you ever held them in your hands? 17 A. No. I've seen pictures, but that's as far as 18 it goes. 19 Q. Doctor, have you ever held a piece of Prolene 20 in your hand? 21 A. I very well could have with my years of 22 experience in polymer science. Just as an example, our 23 polymer characterization lab at the University of 24 Tennessee, we perform a lot of outside analyses for
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1 are made up of 100 percent Prolene? 2 A. It's my understanding that those materials are 3 made of Prolene, yes. 4 Q. And 100 percent of Prolene? 5 A. Well, Prolene is a formulation, so there's 6 additives in there. It's polypropylene plus appropriate 7 additives. 8 Q. But my question, sir, is it your testimony that 9 these products are made of 100 percent Prolene? 10 A. Well, the mesh is in there, but there's also a 11 delivery device and packaging, so there are things other 12 than Prolene, but the mesh itself is Prolene. 13 Q. Okay. So, Doctor, is it your testimony that 14 the Prolift +M is made of 100 percent Prolene? 15 A. No. There could well be other things in some 16 of these materials, yes. 17 Q. In the mesh? 18 A. There could be biodegradable material, for 19 example. 20 Q. Okay. What other material other than Prolene 21 does Prolift +M consist of in the mesh? 22 A. I'd have to go back and review that. 23 Q. You don't know today? 24 A. As I sit here, I can't say.	1 companies, for individuals, and it's certainly possible 2 that some passed through at some time. 3 Q. Doctor, sitting here today, can you ever recall 4 an instance where you've held a piece of Prolene in your 5 hand? 6 A. No. 7 Q. And, Doctor, have you ever done any hands-on 8 testing of Prolene? 9 A. No. 10 Q. Doctor, when is -- I want to go back to these 11 products, if you will, okay? 12 A. Okay. 13 Q. When's the first time you've ever heard of 14 these products? 15 A. I've certainly heard of Prolene, having been in 16 the polypropylene game for a long time, but these 17 particular mesh products, I knew pelvic mesh was out 18 there, I may have heard the names, but they certainly 19 didn't stick. 20 Q. When was the first time that you'd heard the 21 name of these products, sir? 22 A. I would say, these products, at the time I got 23 involved in this litigation. 24 Q. And that would have been in the fall of 2005?

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<p>1       A. 2015.</p> <p>2       Q. Thank you, sir. I like it when a scientist is</p> <p>3       accurate.</p> <p>4       Doctor, do you have any idea what the</p> <p>5       indications are for these products?</p> <p>6       A. You mean the medical indications?</p> <p>7       Q. Yes, sir.</p> <p>8       A. Well, stress urinary incontinence, pelvic organ</p> <p>9       prolapse.</p> <p>10      Q. Do you know how long these products have been</p> <p>11     on the market?</p> <p>12      A. The exact date for these individual products, I</p> <p>13     don't.</p> <p>14      Q. Do you know the physical dimensions of the mesh</p> <p>15     in these individual products?</p> <p>16      A. No.</p> <p>17      Q. And, Doctor, do you know the weight of the mesh</p> <p>18     in these individual products?</p> <p>19      A. No, not as I sit here.</p> <p>20      Q. Doctor, do you know a woman's lifetime risk of</p> <p>21     developing SUI or POP?</p> <p>22      A. I don't.</p> <p>23      Q. Do you know the natural progression of the</p> <p>24     disease?</p>	<p>1       process Ethicon uses to make Prolene?</p> <p>2       A. Well, I know how the polypropylene is produced</p> <p>3       and I know that the material is thin-mixed with various</p> <p>4       additives, processing aids, antioxidants.</p> <p>5       Q. Anything else?</p> <p>6       A. Then it's extruded. Fibers are produced by</p> <p>7       passing through a spinneret. Those fibers then get</p> <p>8       woven into a mesh product.</p> <p>9       Q. Do you know at what temperature?</p> <p>10      A. The exact temperature of the extrusion, it</p> <p>11     would have to be well above the melting temperature of</p> <p>12     the polypropylene, which is 165 degrees C, so it's</p> <p>13     something of the order of 200 degrees C.</p> <p>14      Q. Do you know where Prolene is made?</p> <p>15      A. The documentation I've seen leads me to believe</p> <p>16     that it's made in Pennsylvania somewhere, near</p> <p>17     Philadelphia.</p> <p>18      Q. And, Doctor, is the mesh that's contained in</p> <p>19     these individual products, is it woven or knitted?</p> <p>20      A. It's actually knitted.</p> <p>21      Q. And what do you base that testimony on?</p> <p>22      A. Just documentation that I've reviewed.</p> <p>23      Q. Are you an expert in the manufacturing process</p> <p>24     of pelvic mesh?</p>
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<p>1       A. No.</p> <p>2       Q. Do you know any of the nonsurgical options?</p> <p>3       A. No.</p> <p>4       Q. And, Doctor, all of your opinions contained in</p> <p>5       your report, which was marked as Exhibit 3, refer to</p> <p>6       these individual products; correct?</p> <p>7       A. Yes.</p> <p>8       Q. Doctor, do you know how many newtons of force</p> <p>9       are placed on the mesh once it's in vivo?</p> <p>10      A. No.</p> <p>11      Q. Do you have any idea about how these individual</p> <p>12     products are implanted in the body?</p> <p>13      A. I have some idea.</p> <p>14      Q. Have you ever -- certainly you've never</p> <p>15     implanted any of these devices in the body?</p> <p>16      A. I have not.</p> <p>17      Q. Have you ever watched any videos regarding how</p> <p>18     these devices were implanted in the body?</p> <p>19      A. Not videos, but I have seen pictures showing</p> <p>20     how it's done, basically.</p> <p>21      Q. And do you know the differences in how these</p> <p>22     individual products are implanted in the body?</p> <p>23      A. No.</p> <p>24      Q. What do you know about the manufacturing</p>	<p>1       A. Well, I'm knowledgeable in the production of</p> <p>2       polypropylene fibers. When I was at Hercules, as I</p> <p>3       mentioned earlier, I was there for five years right</p> <p>4       after graduate school, for about three years of that</p> <p>5       time I was technical liaison between Hercules' central</p> <p>6       R &amp; D center in Wilmington, Delaware, and Hercules'</p> <p>7       fibers technical center in Oxford, Georgia, where they</p> <p>8       produce polypropylene fibers on a massive scale.</p> <p>9       Q. Well, but do you hold yourself out as an expert</p> <p>10      in the manufacturing process of pelvic mesh?</p> <p>11      A. I'm certainly knowledgeable about production of</p> <p>12     polypropylene fibers. Once it gets into the actual</p> <p>13     knitting process and the exact geometry of these various</p> <p>14     mesh products, I'm not an expert in those areas.</p> <p>15      Q. Doctor, you know the difference between</p> <p>16     polypropylene and Prolene; correct?</p> <p>17      A. Yes.</p> <p>18      Q. And as a materials scientist, you'll agree that</p> <p>19     polypropylene is chemically different than Prolene;</p> <p>20     correct?</p> <p>21      A. Well, Prolene is mostly polypropylene. It's</p> <p>22     isotactic polypropylene, to be exact.</p> <p>23      Q. I understand.</p> <p>24      A. But it does contain additives, but those</p>

8 (Pages 26 to 29)

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<p style="text-align: center;">Page 30</p> <p>1 additives are present at a very low level.      2 Q. But to be exact, polypropylene is chemically      3 different than Prolene; correct?      4 A. Well, polypropylene as it's encountered in the      5 marketplace essentially always has these additives in      6 it. Processing aids and antioxidants are always put      7 into polypropylene.      8 Q. Right, but, Doctor, my question is more      9 specific. Is it your testimony that polypropylene and      10 Prolene are chemically different or chemically the same?      11 A. Prolene is a particular formulation of      12 polypropylene.      13 Q. So they're chemically different; correct?      14 A. There are additives added.      15 Q. But they are chemically different?      16 Polypropylene is chemically different than Prolene;      17 correct?      18 A. Well, Marlex versus Prolene, the base polymer      19 in both is isotactic polypropylene. There may be      20 different additives in there. There may be different      21 molecular weights of polypropylene use. There may be      22 different molecular weight distributions of the      23 polypropylene that's used. So Prolene is a particular      24 formulation of polypropylene.</p>	<p style="text-align: center;">Page 32</p> <p>1 A. My biggest focus on polypropylene was when I      2 was at Hercules. We performed a lot of analytical work      3 on polypropylene. But I actually synthesized      4 polypropylene and polypropylene copolymers and      5 characterized the products when I was a graduate student      6 at the University of Akron in the very early 1980s.      7 Q. Have you ever done any independent study or lab      8 work regarding the biocompatibility of polypropylene?      9 A. Could you repeat that question?      10 Q. Sure. Have you ever done any independent study      11 or lab work regarding the biocompatibility of      12 polypropylene?      13 A. What do you mean by "biocompatibility"?      14 Q. Whether or not polypropylene is biocompatible      15 with the human body.      16 A. You mean cell culture studies, things like      17 that?      18 Q. Whether it's biocompatible with the human body.      19 A. Well, I've examined explanted polypropylene and      20 seen degradation in the material.      21 Q. Doctor, I may have asked you this. If I did, I      22 apologize. You've never designed a polypropylene      23 implant; correct?      24 A. I have not.</p>
<p style="text-align: center;">Page 31</p> <p>1 Q. I understand that, Doctor, but Prolene has a      2 different chemical composition compared to pure      3 polypropylene; correct?      4 A. Compared to pure polypropylene, that's correct.      5 Q. Thank you. And Prolene and polypropylene are      6 not identical from a chemical composition standpoint,      7 are they?      8 A. Polypropylene is the major component in      9 Prolene.      10 Q. Right, but they are not chemically identical,      11 are they, sir?      12 A. The additives make them different. Prolene has      13 the additives. Pure polypropylene would not.      14 Q. And you'd never teach your polymer students at      15 UT that Prolene and polypropylene have the same chemical      16 composition, would you?      17 A. No, I would teach them that Prolene is an      18 isotactic polypropylene with a certain additive package      19 in it.      20 Q. Let's talk about polypropylene specifically, if      21 you will. You've studied polypropylene before, I take      22 it, as a scientist?      23 A. Yes.      24 Q. When did you begin doing that?</p>	<p style="text-align: center;">Page 33</p> <p>1 Q. And -- well, let's talk about Prolene for a      2 minute. Has any of the work that you've done as a      3 scientist involved Prolene other than the litigation      4 that we're here about today?      5 A. As I said earlier, I've been involved with      6 polymers for a long time. We've got our polymer      7 characterization lab at the university. Something could      8 have passed through, but I don't recall it.      9 Q. Thank you. And, Doctor, have you ever done any      10 type of study to determine the biocompatibility of      11 Prolene?      12 A. No.      13 Q. And have you ever done any testing to determine      14 if Prolene degrades?      15 A. Well, we've done studies to determine whether      16 or not polypropylene formulations degrade.      17 Q. But, Doctor, my question is specifically about      18 Prolene. Have you ever performed any testing to      19 determine if Prolene degrades?      20 A. I've reviewed the literature, including the      21 literature in-house at Ethicon, where they observed what      22 they attributed as oxidative degradation.      23 Q. Doctor, have you ever performed any -- strike      24 that.</p>

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<p>1       Have you personally performed any testing to 2 determine if Prolene degrades?</p> <p>3       A. We have performed testing to determine whether 4 or not polypropylene --</p> <p>5       Q. And I'm not -- I don't mean to cut you off, but 6 I am under a time limit. I'm talking about Prolene.</p> <p>7       Have you personally done any testing to 8 determine if Prolene degrades?</p> <p>9       A. We have tested polypropylene pelvic mesh. That 10 was a Boston Scientific product. But these materials 11 are 99.8 percent polypropylene.</p> <p>12      Q. And move to strike as nonresponsive.</p> <p>13      Doctor, I'm asking you a specific question. I 14 need a yes or no. Have you personally performed any 15 testing to determine if Prolene degrades?</p> <p>16      A. We have tested polypropylene, but we have not 17 tested Prolene.</p> <p>18      Q. Thank you. And, Doctor, you've not tested the 19 mechanical properties of Prolene, have you?</p> <p>20      A. We have not.</p> <p>21      Q. Doctor, have you done any tests on Prolene that 22 can be repeated and confirmed? I'm talking about 23 Prolene, not polypropylene.</p> <p>24      A. Yeah. We have not in my laboratory tested</p>	<p>1       Q. A reduction in the physical properties. 2       A. Which ones? 3       Q. Any of them. 4       A. Have I actually seen that material with my own 5 eyes? 6       Q. Yes, sir. 7       A. No. 8       Q. Thank you. And, in fact, Doctor, you've never 9 tested the durability of Prolene, have you? 10      A. No. 11      Q. You've never tested the tensile strength of 12 Prolene, have you? 13      A. No. 14      Q. You've never tested the toughness of Prolene, 15 have you? 16      A. No. 17      Q. You've never tested any type of physical 18 property of Prolene, have you? 19      A. No. 20      Q. You've never done any type of benchtop testing 21 of Prolene, have you? 22      A. No. 23      Q. And you've never done any root cause analysis 24 to determine if Prolene is defective, have you?</p>
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<p>1       Prolene.</p> <p>2       Q. Doctor, have you ever done -- and when you say 3 you have not in your laboratory tested Prolene, would 4 that include a pristine piece of Prolene and also an 5 explanted piece of Prolene?</p> <p>6       A. Yeah, again, as I said earlier, we may have 7 characterized some material that was sent to us by 8 someone at some point, probably in terms of a molecular 9 weight analysis or something like that, but I don't 10 recall testing Prolene.</p> <p>11      Q. Doctor, have you ever personally seen a Prolene 12 explant that has degraded?</p> <p>13      A. I've seen pictures, but I haven't actually with 14 my own two eyes seen the degraded Prolene explant.</p> <p>15      Q. And, Doctor, with your own two eyes, have you 16 ever seen oxidated Prolene?</p> <p>17      A. With my own two eyes, I'd have to say no.</p> <p>18      Q. Doctor, with your own two eyes, have you ever 19 personally seen Prolene with embrittlement?</p> <p>20      A. No.</p> <p>21      Q. Have you ever with your own two eyes personally 22 seen Prolene that has a loss of mechanical properties?</p> <p>23      A. What do you mean by "loss of mechanical 24 properties"?</p>	<p>1       A. Yes, I think I have. 2       Q. What? 3       A. Basically, I reviewed extensive literature, 4 both Ethicon internal literature where they observed 5 degradation of explanted Prolene, and I also reviewed 6 extensive literature. I could go through paper by 7 paper, if you like, and they observed degradation of 8 Prolene implants.</p> <p>9       Q. And we're going to get to that, but outside of 10 literature, Doctor, have you ever done any -- outside of 11 your literature review, have you ever done any type of 12 root cause analysis to determine if Prolene is 13 defective?</p> <p>14      A. We have explored the mechanism by which 15 polypropylene mesh degrades inside the body.</p> <p>16      Q. Okay. And I'm sorry if my question wasn't 17 clear. I was asking about Prolene.</p> <p>18      So outside of literature, Doctor, have you ever 19 done any type of root cause analysis to determine if 20 Prolene is defective?</p> <p>21      A. What do you mean by "root cause analysis"?</p> <p>22      Q. Any type of analytical study to determine if 23 Prolene is defective.</p> <p>24      A. You mean actually perform experiments on</p>

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1 Prolene? No.	1 28 women?
2 Q. Doctor, have you ever performed any type of	2 A. No.
3 accelerated aging tests for Prolene?	3 Q. Have you ever even seen the explants from these
4 A. No.	4 28 women?
5 Q. Doctor, you've cleaned mesh before, have you	5 A. No.
6 not?	6 Q. Do you know if any exist?
7 A. Yes.	7 A. I don't.
8 Q. Have you personally been involved in that	8 Q. Do you know why their mesh was removed?
9 process?	9 A. Because they had a problem. It's not ethical
10 A. Yes, I have.	10 to take mesh out if a person's not having a problem with
11 Q. And was that with the 11 explants in Boston	11 it.
12 Scientific?	12 Q. What do you base that on?
13 A. Yes.	13 A. It's a horribly invasive surgery.
14 Q. Have you ever personally cleaned Prolene mesh?	14 Q. What problem did Bonnie Blake have, Doctor,
15 A. No.	15 that required her mesh to be removed?
16 Q. Have you ever been involved in any type of	16 A. I don't know.
17 cleaning protocols for Prolene mesh?	17 Q. And, Doctor, what problem did Robin Bridges
18 A. With developing the cleaning protocol?	18 have that required her mesh to be removed?
19 Q. For Prolene mesh. Not polypropylene. Prolene	19 A. The specific complaints of the individuals, I
20 mesh.	20 don't know.
21 A. No, we haven't cleaned Prolene mesh.	21 Q. And, Doctor, do you know the specific reasons
22 Q. And -- but you haven't been involved in any	22 why any of the 28 plaintiffs' mesh were removed?
23 cleaning protocols for Prolene mesh; correct?	23 A. As I said before, because they were having a
24 A. There's an ASTM protocol, and that's what we	24 problem with it.
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1 use when we clean polypropylene.	1 Q. But my question is: Do you know the specific
2 Q. Right, but I'm asking about your personal	2 reason why any of these 28 plaintiffs' mesh was removed?
3 experience, Doctor. You've never been involved in any	3 A. No, I don't.
4 cleaning protocols for Prolene mesh; correct?	4 Q. You don't know when these 28 plaintiffs' meshes
5 A. No. Correct.	5 were implanted, do you?
6 Q. Doctor, look back at Exhibit 1 for me, please.	6 A. I do not have those records, no.
7 That's a notice of deposition?	7 Q. And you don't know when they were explanted?
8 A. Yes.	8 A. No.
9 Q. I'll represent to you that you're designated in	9 Q. Do you know how many pieces of an explant was
10 28 different lawsuits. Does that look about right?	10 removed?
11 A. That looks about right.	11 A. No.
12 Q. Do you know what -- and each lawsuit represents	12 Q. And do you know if these 28 plaintiffs'
13 the name of a plaintiff that received a Prolene implant;	13 explants were stored in formalin?
14 correct?	14 A. No.
15 A. Correct.	15 Q. You would agree that if explants exist for
16 Q. Do you know what product these 28 women	16 these 28 plaintiffs, that would be an important piece of
17 received?	17 evidence in this litigation; correct?
18 A. All I know is it was Prolene, a Prolene-based	18 A. That would be, yes.
19 mesh.	19 Q. And would you like to review those explants?
20 Q. You never reviewed medical records?	20 A. Sure.
21 A. No.	21 Q. And have you asked the plaintiffs' lawyers for
22 Q. Never talked to any of the doctors?	22 the permission to review those explants?
23 A. No.	23 A. I have not.
24 Q. Never inspected any of the explants from these	24 Q. Why not?

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<p>1       A. Well, I might very well at some point in time.      2       The first step was to get familiar with the case and      3       file my report.      4       Q. Doctor, have you ever seen any type of      5       histology slides from any of these 28 plaintiffs?      6       A. Not to my knowledge.      7       Q. Would you review histology slides if they were      8       available?      9       A. I'd certainly look at them.      10      Q. Have you asked for them?      11      A. I have not.      12      Q. Doctor, have you ever performed -- strike that.      13           Fair to say that you've never performed any      14           type of analytical testing on the explants of these 28      15           plaintiffs; correct?      16      A. Correct.      17      Q. You've never done any type of SEM, FTIR, DSC,      18      EDS, GPC on these plaintiffs' explants; correct?      19      A. Correct.      20      Q. Doctor, have you -- strike that.      21           I think we talked about this earlier, but it's      22           undisputed that degradation affects the physical      23           properties of mesh; correct?      24      A. Yes.</p>	<p>1       A. My experience with polypropylene, my      2       characterization of polypropylene-based meshes.      3       Q. Do you base --      4       A. The literature that Ethicon has in-house going      5       back to the early '80s where they again and again see      6       evidence of oxidative degradation of polypropylene      7       implants.      8       Q. Doctor, you've never personally run any type of      9       oxidation tests on Prolene; correct?      10      A. To my knowledge, not on Prolene.      11      Q. And you've never done a molecular weight test?      12      A. We've done a lot of molecular weight tests.      13      Q. On Prolene?      14      A. As I said earlier, we may have in the polymer      15      characterization lab at some time, but I don't recall      16      explicitly doing molecular weight determinations on      17      Prolene.      18      Q. Okay. And you would have done that by GPC;      19      correct?      20      A. Yes. It's not the only way to determine      21      molecular weight, but it's a very common way to do it.      22      Q. And, Doctor, those analytical testing      23      techniques were available to you at your lab at UT;      24      correct?</p>
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<p>1       Q. And you've never performed any physical or      2       mechanical testing on the explants of these 28      3       plaintiffs; correct?      4       A. Correct.      5       Q. That would include tensile strength,      6       elongation, toughness, or Young's modulus; correct?      7       A. Correct.      8       Q. Also, we would include creep, stress,      9       relaxation, and fatigue; correct?      10      A. Correct.      11      Q. You've not done any of that?      12      A. Correct.      13      Q. Doctor, the tests, the analytical tests that we      14      just talked about, the SEMs, the FDIRs, those show      15      oxidation; correct?      16      A. Yes.      17      Q. And have you done any type of testing      18      whatsoever on these 28 plaintiffs to show oxidation?      19      A. I have not.      20      Q. And, Doctor, can you make any type of      21      prediction about whether or not the mesh from these 28      22      plaintiffs will oxidize?      23      A. Yes, I can.      24      Q. And what do you base that on?</p>	<p>1       A. We have those techniques available, yes.      2       Q. And, Doctor, when I asked you could you make      3       any prediction about whether or not the mesh from these      4       28 plaintiffs will oxidize, do you -- are you supporting      5       that opinion on any literature specifically about      6       Prolene?      7       A. Yes.      8       Q. What literature?      9       A. Okay. Let's look in my report.      10      Q. And I'm not talking about polypropylene. I'm      11      talking about Prolene. Okay?      12      A. Okay.      13      MR. MONSOUR: Just so you know, I've seen you      14      look at your watch about 20 times, we're not going      15      to hold your feet to the fire on three hours. I      16      mean, if you need some more time, let us know.      17      Within reason, but just let us know.      18      MR. HUTCHINSON: I appreciate it.      19      MR. MONSOUR: Don't worry.      20      A. The Reference 20 in my report, this is      21      Jongebloed, I guess that's how you say it, and Worst,      22      they reported an SEM study on a Prolene suture that had      23      been implanted in the human eye for one year, and they      24      reported that both Prolene loops showed severe</p>

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<p style="text-align: center;">Page 46</p> <p>1 degradation of the surface layer.      2 Then Mary, et al., in 1998, that's Reference 21      3 in my report, they looked at polypropylene, Prolene      4 sutures used in vascular surgery, and the explanted      5 suture showed visible evidence of surface stress      6 cracking.      7 Costello, et al., those are two papers from      8 2007.      9 Q. And did those -- but my question, sir, is about      10 Prolene. Did those Costello papers reference Prolene?      11 A. Yes.      12 Q. Okay. All right. Other than Jongebloed -- and      13 you spell that J-o-n-g-e-l-b-o-e-d [sic] --      14 A. I'm not sure we're pronouncing it right. Who      15 knows?      16 Q. -- Mary and Costello --      17 A. Yeah, there's two Costello papers.      18 Q. Correct. Any other literature that you're      19 supporting your opinions on?      20 A. Actually, Clave reports analysis of 100      21 explants, these were pelvic meshes from various      22 suppliers, but they're really not explicit about where      23 they came from, but it may well be that there are some      24 Ethicon materials in there.</p>	<p style="text-align: center;">Page 48</p> <p>1 or one could look at molecular weight changes in the      2 material. If chains are being broken, degradation is      3 happening.      4 Those changes manifest themselves in changes in      5 mechanical properties, but they're not the direct      6 observation of the degradation process. You're      7 measuring the consequences of degradation with those      8 studies.      9 Q. Doctor, but, nevertheless, evaluating      10 mechanical properties and physical properties are an      11 important part in your analysis of whether or not a      12 material degrades; correct?      13 A. No. As I just said, degradation can be      14 established with spectroscopy, with microscopy, with gel      15 permeation chromatography, with light scattering, and      16 other molecular methods.      17 Q. Can degradation be established by reduction in      18 physical properties?      19 A. If one measures a material and sees a reduction      20 in mechanical properties, again, just speaking      21 generically about mechanical properties at this point,      22 if one sees a change, then one might suspect degradation      23 is taking place, yes.      24 Q. All right. And just so the record's clear,</p>
<p style="text-align: center;">Page 47</p> <p>1 Q. But you don't know for sure, do you, sir?      2 A. Not in the case of Clave.      3 Q. Okay. Thank you.      4 A. I haven't seen firm evidence. But then I've      5 also got the internal Ethicon documents.      6 Q. We're going to get to those in a minute, but      7 I'm talking about the peer-reviewed literature. Okay?      8 A. Okay.      9 Q. So we'll get to those in a minute, but let's      10 stick with the peer-reviewed literature.      11 A. Okay.      12 Q. Jongebloed, Mary, and Costello are the only      13 literature regarding Prolene that you base your opinions      14 on; is that correct?      15 A. Yes.      16 Q. Okay. And, Doctor, I forgot to ask you about      17 this earlier, but when we were talking about physical      18 and mechanical property testing, you'll agree that      19 mechanical properties and the evaluation of mechanical      20 properties is relevant when determining whether or not      21 mesh degrades?      22 A. I don't think it's necessarily relevant. One      23 can determine if a material is degrading by      24 spectroscopic means, chemical changes in the material,</p>	<p style="text-align: center;">Page 49</p> <p>1 degradation can be established by reduction in physical      2 properties; correct?      3 A. No, molecular level degradation needs      4 spectroscopy or molecular weight measurements.      5 Mechanical properties -- changes in mechanical      6 properties are merely an outcome of the chemical      7 changes. They're not direct.      8 Q. Doctor, would you ever tell your students at UT      9 to disregard the results of physical properties when      10 making a determination of whether or not a polymer has      11 degraded?      12 A. Well, if they had that material at hand,      13 certainly they would factor it into the analysis, but      14 it's not the direct analysis of whether or not a      15 material has degraded.      16 Q. I understand that, sir, but you will agree that      17 it is one piece of the puzzle on whether or not a      18 polymer has degraded; correct?      19 A. It's a piece of the puzzle, but it's a      20 secondary piece of the puzzle. It's not a primary one.      21 Q. Doctor, do you have any evidence that any of      22 these 28 plaintiffs experienced any type of chronic pain      23 related to Prolene?      24 A. No direct evidence, but they had their mesh</p>

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<p>1 taken out, and I assume they had problems with it, or 2 they wouldn't be suing Ethicon.</p> <p>3 Q. That's an assumption on your part; correct?</p> <p>4 A. It is. It is.</p> <p>5 Q. And, Doctor, can you identify by name a single 6 person who has had a failure of their mesh for the 7 reasons that you outline in your report?</p> <p>8 A. I would say that oxidative degradation is at 9 the heart of the problems that all of these people had 10 with the mesh and it's the reason that there's multiple 11 mesh companies with thousands of lawsuits around. 12 People are having problems with polypropylene mesh. 13 It's fundamentally the wrong material to make a pelvic 14 mesh out of.</p> <p>15 Q. Doctor, can you identify by name a single 16 person who has had a failure of their mesh for the 17 reasons outlined in your report?</p> <p>18 A. Again, all these people --</p> <p>19 Q. I'm just asking for a name.</p> <p>20 A. All of these people, Bonnie Blake, Robin 21 Bridges, Carey Beth Cole, these people had problems with 22 their mesh.</p> <p>23 Q. How did Bonnie Blake's mesh fail?</p> <p>24 A. Oxidative degradation is at the core of what's</p>	<p>1 of these removals, so every individual listed here.</p> <p>2 Q. Okay. And, Doctor, how do you know that Bonnie 3 Blake's mesh was removed because of degradation without 4 reviewing the medical records?</p> <p>5 A. It's made out of polypropylene. Polypropylene 6 is attacked inside the human body with strong oxidizing 7 agents.</p> <p>8 Q. Does Bonnie Blake have any mesh that's made out 9 of Prolene?</p> <p>10 A. I have to assume that her mesh was made out of 11 Prolene because she's suing Ethicon.</p> <p>12 Q. Do you know if Bonnie Blake has mesh that's 13 made out of Prolene?</p> <p>14 A. I think it's a logical conclusion to reach.</p> <p>15 Q. My question is: Do you know, sir, whether or 16 not Bonnie Blake has mesh that's made out of Prolene?</p> <p>17 A. I have not reviewed her medical records. Okay?</p> <p>18 Q. But my question is: Do you know if Bonnie 19 Blake has mesh that's made out of Prolene? Yes or no?</p> <p>20 A. Yes.</p> <p>21 Q. And what do you base that on?</p> <p>22 A. The fact that she's suing Ethicon.</p> <p>23 Q. Doctor, you're not a clinician?</p> <p>24 A. I'm not.</p>
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<p>1 happening to these materials inside the human body.</p> <p>2 Q. And, Doctor, my question is: If you've not 3 reviewed Bonnie Blake's explant, how can you tell the 4 jury that Bonnie Blake's explant failed because of 5 oxidative degradation?</p> <p>6 A. We have examined explants, to the extent that 7 we could lay our hands on them, and there's indication 8 of oxidative degradation in all the ones that we've 9 seen.</p> <p>10 Q. I understand that, but you've never examined 11 Bonnie Blake's explant, have you?</p> <p>12 A. I have not.</p> <p>13 Q. And, Doctor, can you identify by name a person 14 who has had mesh removed because of specifically 15 degradation?</p> <p>16 A. Well, again, it's what I'm saying. There's 17 this list of women here, and they had problems with 18 their mesh. And polypropylene is fundamentally 19 susceptible to oxidative degradation. It's inherent to 20 its chemical structure.</p> <p>21 Q. Doctor, can you identify the name of a person 22 who has had their mesh specifically removed because of 23 degradation?</p> <p>24 A. I believe oxidative degradation is behind all</p>	<p>1 Q. And you haven't -- have you ever reviewed a 2 medical record that says the surgeon is removing Prolene 3 mesh as a result of degradation?</p> <p>4 A. I don't review medical records normally. I'm a 5 polymer scientist. I'm a polymer chemist. The 6 chemistry of polymers, the characterization of polymers, 7 is my thing. I'm not a medical doctor.</p> <p>8 Q. I understand that, Doctor, but my question is: 9 Have you ever reviewed a medical record that says a 10 surgeon is removing Prolene mesh as a result of 11 degradation?</p> <p>12 A. I have not.</p> <p>13 Q. Doctor, have you done anything whatsoever to 14 explain how the alleged effects of degradation have 15 caused clinical harm to any of these 28 plaintiffs?</p> <p>16 A. Well, my report describes what happens to the 17 properties of polypropylene when they undergo 18 degradation, and it's the mechanical mismatch between 19 the degraded implants and the soft tissue that surrounds 20 it that's the root cause of these problems.</p> <p>21 Q. Do you know the symptoms that any of these 28 22 plaintiffs were complaining about?</p> <p>23 A. Individual symptoms will vary, but pain is a 24 very common one.</p>

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<p>1       Q. Do you -- but do you know the specific symptoms 2 of these 28 plaintiffs in these cases that you're 3 designated as an expert in?</p> <p>4       A. No, I don't.</p> <p>5       Q. And, Doctor, are you qualified to teach 6 students at UT how degradation can cause clinical harm?</p> <p>7       A. Yes, I am. I've taught a lot of biomedical 8 students in the past.</p> <p>9       Q. And, Doctor, have you ever taught any students 10 at UT that degradation causes clinical harm?</p> <p>11      A. Certainly I have done that, yes.</p> <p>12      Q. And, Doctor, have you ever taught any of your 13 students at UT how Prolene causes clinical harm?</p> <p>14      A. Explicitly with Prolene, no, but with a variety 15 of biomaterials, whether it's bone cement or what have 16 you. Degradation is a bad thing.</p> <p>17      Q. And, Doctor, have you ever taught your students 18 at UT anything about Prolene?</p> <p>19      A. Yes. I teach them about polypropylene, and 20 Prolene is made of polypropylene.</p> <p>21      Q. Doctor, have you ever taught your students 22 about Prolene specifically?</p> <p>23      A. Specifically by name, Prolene, no, but 24 isotactic polypropylene with the usual package of</p>	<p>1       Q. And, Doctor, are you aware that a West Virginia 2 federal judge ruled that your testing of the Boston 3 Scientific products was unreliable and excluded it?</p> <p>4       A. That's correct, but those data were eventually 5 published in the top biomaterials journal in the world 6 after undergoing, not only rigorous peer review, but 7 also the paper was reviewed for merit by the editorial 8 advisory board because the work was done under 9 litigation, for litigation purposes.</p> <p>10      Q. Doctor, have you ever done any type of testing 11 of mesh explants that's been admitted in a court?</p> <p>12      A. Not yet.</p> <p>13      Q. In the Boston Scientific, Doctor -- I'm sorry. 14 Strike that.</p> <p>15      In the Boston Scientific litigation, you 16 testified that you're not an expert in the design of 17 surgical mesh. Do you stand by that?</p> <p>18      A. I'm not an expert in the design of surgical 19 mesh. I'm an expert in the polymers that the surgical 20 meshes are made of, whether they're polypropylene, 21 polyethylene terephthalate, polyvinylidene fluoride. 22 I'm knowledgeable broadly about polymer chemistry and 23 characterization of polymers.</p>
	MR. MONSOUR: At the end of this, you're going
<p>1 additives, such as processing aids and antioxidants, 2 yes.</p> <p>3       Q. Doctor, I know that you've worked for -- 4 against, rather -- Boston Scientific. Have you ever 5 done any type of analytical testing of pelvic mesh 6 explants other than in Boston Scientific?</p> <p>7       A. No.</p> <p>8       Q. And, Doctor, are you -- did you perform any 9 type of physical property testing of the pelvic explants 10 in the Boston Scientific litigation?</p> <p>11      A. We measured the materials by spectroscopy, we 12 did GPC, we looked at the materials with 13 thermogravimetric analysis, SEM with EDS, but we did not 14 measure mechanical properties of those materials.</p> <p>15      Q. Why not?</p> <p>16      A. We were interested in determining what caused 17 the degradation of those materials once we noted the 18 degradation, and we used spectroscopy and GPC to do it. 19 As I mentioned earlier, those are the primary tools that 20 one would use to get direct evidence of degradation and 21 to identify what's causing the degradation.</p> <p>22      Q. Doctor, you'll agree that the adherence to 23 protocols and controls is the hallmark of good science?</p> <p>24      A. Yes.</p>	<p>1 to have to spell, probably, a few of those.</p> <p>2 THE WITNESS: We'll do that.</p> <p>3 MR. HUTCHINSON: Yeah.</p> <p>4 THE WITNESS: We'll do that.</p> <p>5 BY MR. HUTCHINSON:</p> <p>6       Q. But -- I'm sorry. You're not an expert in the 7 design of surgical mesh?</p> <p>8       A. Actually designing the mesh, the geometry, the 9 shape, no, I'm not.</p> <p>10      Q. And, Doctor, you testified in Boston Scientific 11 that polypropylene meshes should not be available to 12 doctors to treat SUI or POP. Do you recall that?</p> <p>13      A. Yes.</p> <p>14      Q. And do you stand by that?</p> <p>15      A. Yes, I do.</p> <p>16      Q. Doctor, you testified that polypropylene 17 vaginal mesh is a very bad idea. Do you stand by that?</p> <p>18      A. I do.</p> <p>19      Q. And you've never shared those views with any 20 physicians at UT; is that right?</p> <p>21      A. Yes, I have.</p> <p>22      Q. When did you do that?</p> <p>23      A. I did that late summer/early fall of last year.</p> <p>24      Q. And you did that after you were cross-examined</p>

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<p>1 about that; correct?</p> <p>2 A. Yeah, I did.</p> <p>3 Q. Doctor, have you ever told the doctors at UT</p> <p>4 that Prolene mesh should not be used to treat SUI or</p> <p>5 POP?</p> <p>6 A. I cautioned them about polypropylene mesh</p> <p>7 broadly.</p> <p>8 Q. Okay. But my question is specifically about</p> <p>9 Prolene. Have you ever told the doctors at UT that</p> <p>10 Prolene mesh should not be used to treat SUI or POP?</p> <p>11 A. When I told them that polypropylene mesh should</p> <p>12 not be used, that it's a bad idea, that it's susceptible</p> <p>13 to degradation inside the human body, they should know</p> <p>14 that Prolene is polypropylene-based pelvic mesh, just</p> <p>15 like Marlex is.</p> <p>16 Q. But, Doctor, have you ever told doctors at UT</p> <p>17 that using Prolene mesh should not be done in treating</p> <p>18 SUI or POP?</p> <p>19 A. Not yet.</p> <p>20 Q. Doctor, you testified in the Boston Scientific</p> <p>21 litigation that you couldn't cite any literature that</p> <p>22 states there's a clinical effect of degradation on a</p> <p>23 patient. Do you remember that?</p> <p>24 A. Yes, I do.</p>	<p>1 with this soft vaginal tissue, but as the oxidative</p> <p>2 process takes place, the mesh stiffens, and then it can</p> <p>3 no longer move with that material.</p> <p>4 So you've got soft flesh moving and the mesh</p> <p>5 isn't moving, so there's an abrasion, and this is a sort</p> <p>6 of thing that can lead to the abrasions that are seen</p> <p>7 with this mesh.</p> <p>8 Q. Doctor, stick with me. Are you aware of any</p> <p>9 literature that states there's a clinical effect of</p> <p>10 Prolene degradation on a patient? That's my question.</p> <p>11 A. I may have -- I may very well have seen that in</p> <p>12 all of my literature review, but I can't call it out as</p> <p>13 I sit here right at this moment.</p> <p>14 Q. And you didn't cite any reference in your</p> <p>15 report that says there's a clinical effect of Prolene</p> <p>16 degradation on a patient; correct?</p> <p>17 A. Actually, on thinking about it, I think this</p> <p>18 Klinge article, Reference 42, calls this out.</p> <p>19 Q. And what does it say about the clinical effect</p> <p>20 of Prolene degradation on a patient?</p> <p>21 MR. MONSOUR: I'm going to object to form. Can</p> <p>22 I ask you one question just for clarity's sake? Are</p> <p>23 you talking about polypropylene articles, or are you</p> <p>24 talking --</p>
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<p>1 Q. And, Doctor, to this day, are you still unaware</p> <p>2 of any literature that states there's a clinical effect</p> <p>3 of degradation on the patient?</p> <p>4 A. No. I've gone and reviewed literature.</p> <p>5 Q. And, Doctor, are you aware of any literature</p> <p>6 that states there's a clinical effect of degradation on</p> <p>7 the patient?</p> <p>8 A. Yes.</p> <p>9 Q. And what literature is that?</p> <p>10 A. The book by Williams is the key reference.</p> <p>11 Q. What's the name of the book?</p> <p>12 A. Let me find it. It's in my reference list</p> <p>13 here.</p> <p>14 Yeah, it's Reference 44, Essential Biomaterials</p> <p>15 Science.</p> <p>16 Q. And that's the key reference that you rely on?</p> <p>17 A. Yes.</p> <p>18 Q. Doctor, does the Williams book say anything at</p> <p>19 all about the clinical effect of degradation of Prolene?</p> <p>20 A. I don't recall it calling out Prolene by name,</p> <p>21 but it basically lays out that implants have to be</p> <p>22 mechanically compatible with the tissue that they're</p> <p>23 implanted in, and initially a polypropylene mesh,</p> <p>24 including the Ethicon meshes, are supple and they move</p>	<p>1 MR. HUTCHINSON: Prolene.</p> <p>2 MR. MONSOUR: -- about, like, medical articles?</p> <p>3 MR. HUTCHINSON: I'm talking about any medical</p> <p>4 article referring to Prolene, which is different</p> <p>5 than polypropylene.</p> <p>6 BY MR. HUTCHINSON:</p> <p>7 Q. Doctor, that's the question.</p> <p>8 MR. MONSOUR: You can answer. You can answer.</p> <p>9 The only thing I'm trying to get at is just -- you</p> <p>10 can keep asking your question.</p> <p>11 A. You know, I'd have to go back and look at this</p> <p>12 Reference 42 to make absolutely sure, but I believe that</p> <p>13 one does call out Prolene by name. I believe he was</p> <p>14 actually a consultant with Ethicon at the time, and so</p> <p>15 he was looking at their materials.</p> <p>16 Q. Doctor, in Boston Scientific you testified</p> <p>17 you're not an expert in the biological response to</p> <p>18 foreign bodies. Do you stand by that?</p> <p>19 A. Well, I don't do research in that area day in</p> <p>20 and day out, so I'm not a card-carrying expert in that</p> <p>21 area, but I understand a bit about it, a bit about what</p> <p>22 the body does to foreign matter when it's placed inside</p> <p>23 it. So I'm not -- I'm not ignorant about it. I'm just</p> <p>24 not --</p>

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<p>1       Q. And, Doctor, you testified in the Boston      2 Scientific trial about degradation, didn't you? About      3 degradation?</p> <p>4       A. Can you be more specific?</p> <p>5       Q. Well, in the Boston Scientific trial, when you      6 gave opinions -- strike that.</p> <p>7       In the Boston Scientific litigation, did you      8 give opinions about degradation without knowing what      9 antioxidants were put into the product?</p> <p>10      A. I gave opinions about degradation of      11 polypropylene in general and about degradation of      12 polypropylene with antioxidants added, and I knew what      13 antioxidants were added, just as I know what      14 antioxidants were added to the Prolene.</p> <p>15      Q. And, Doctor, is it your testimony under oath      16 that you knew what antioxidants were added to Boston      17 Scientific's products before you gave opinions about      18 degradation?</p> <p>19      A. I did not know initially exactly what additives      20 were in there, but later on as I worked more on that      21 case I gained information on the antioxidants were      22 there. The expert on Boston Scientific's side actually      23 denied that antioxidants were in there at the beginning.</p> <p>24      Q. Doctor, you'll agree with me that there's been</p>	<p>1       A. I don't know. That's all that comes to mind      2 now.</p> <p>3       Q. Doctor, since your deposition -- by the way,      4 the last time you were deposed was in December of 2014;      5 correct?</p> <p>6       A. In the Boston Scientific matter, yeah, I think      7 so. That sounds about right. But I've actually been      8 deposed in another matter since then.</p> <p>9       Q. Was it a matter relating to vaginal mesh?</p> <p>10      A. No.</p> <p>11      Q. What was it about?</p> <p>12      A. It was about surgical sealants. It was a      13 patent dispute.</p> <p>14      Q. Have anything to do with polypropylene?</p> <p>15      A. No.</p> <p>16      Q. Doctor, since your last deposition in the mesh      17 litigation in 2014, have you undertaken any type of      18 investigation as to why there's been long-term effective      19 use of Prolene in the human body?</p> <p>20      A. Certainly I've read a lot of literature about      21 the use of Prolene as a biomaterial. And, you know, a      22 little surface cracking caused by oxidation isn't a big      23 issue if you're using the material as a suture. The      24 material can become stiffer and still perform. The</p>
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<p>1       a long-term effective use of Prolene in the human body?</p> <p>2       A. Yes. I don't -- I don't condemn polypropylene      3 broadly as a biomaterial. It has applications,      4 certainly, in sutures. That's fine. It's been used for      5 a long time there.</p> <p>6       Q. Do you condemn Prolene for use in the human      7 body?</p> <p>8       A. As a vaginal mesh, as a pelvic mesh, yes.</p> <p>9       Q. For a vaginal mesh only?</p> <p>10      A. There are issues with it in possibly other      11 applications, but I -- because it is degrading. There      12 is oxidative degradation that's taking place in the      13 material.</p> <p>14      Q. Right, but my question is for vaginal mesh      15 only.</p> <p>16      A. Yes, I think -- I think Prolene is a very bad      17 idea for vaginal mesh.</p> <p>18      Q. And vaginal mesh only; correct?</p> <p>19      A. No, I wouldn't -- I wouldn't say that. It      20 could extend to other applications.</p> <p>21      Q. Where else do you condemn the use of Prolene in      22 the human body?</p> <p>23      A. There may be issues with hernia mesh.</p> <p>24      Q. Where else?</p>	<p>1       suture's put in; the body heals quickly. Right?</p> <p>2       But this mesh is designed to be a permanent      3 implant and it's designed to move with the body. One      4 has to consider the function that the material is going      5 to be used for inside the body.</p> <p>6       Q. Doctor, you know that sutures, Prolene sutures,      7 are designed to be permanently implanted in the body,      8 don't you?</p> <p>9       A. Yes, I do.</p> <p>10      Q. And, Doctor, you know that hernia mesh is      11 designed to be permanently implanted in the body, don't      12 you?</p> <p>13      A. I do.</p> <p>14      Q. Doctor, since 2014, your last deposition, have      15 you found any scientific or medical literature that says      16 Prolene should not be used for mesh implants in the      17 human body?</p> <p>18      A. Actually, I have. I've seen Ethicon's own      19 documentation, which indicates that Prolene is far from      20 an ideal material.</p> <p>21      Q. I'm asking you, sir, about scientific      22 literature, medical literature.</p> <p>23      A. Well, this is literature, internal literature,      24 but it's from Ethicon scientists.</p>

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<p>1       Q. Doctor, my question is about peer-reviewed 2 literature. Have you seen any peer-reviewed literature 3 that says Prolene should not be used as mesh implants in 4 the human body?</p> <p>5       A. Well, I can go back to the Clave paper. They 6 looked broadly at polypropylene meshes from a variety of 7 suppliers.</p> <p>8       Q. Did Clave conclude that Prolene mesh should not 9 be used in the human body?</p> <p>10      A. They've had issues with use of 11 polypropylene-based meshes.</p> <p>12      Q. But did they conclude that Prolene mesh should 13 not be used in the human body?</p> <p>14      A. Not explicitly.</p> <p>15      Q. Are you aware of any other article, Doctor?</p> <p>16      A. Costello.</p> <p>17      Q. That says -- that concludes -- my question is 18 specific. Are you aware of any peer-reviewed literature 19 that says Prolene mesh should not be used in the human 20 body?</p> <p>21      A. I'm not aware of any literature that has that 22 exact statement in there.</p> <p>23      Q. Doctor, have you ever told the doctors at UT 24 that Prolene mesh should not be used for hernia repair?</p>	<p>1       soft pelvic tissue in a woman. And being a mesh, tissue 2 grows into it, nerves grow into it, and when the 3 oxidative degradation occurs and the polypropylene 4 stiffens, the mesh can no longer move in concert with 5 that soft tissue that it's implanted in, so this creates 6 a sliding force or friction.</p> <p>7       And in my report I liken it to taking fine 8 fishing line, which is basically what this mesh is, 9 polypropylene is widely used as fishing line, and 10 rubbing it across delicate skin. If you've been fishing 11 and you've done that, it can hurt. And that's what's 12 happening. That's the root cause of the pain.</p> <p>13      Q. And, Doctor, in your fishing line example, if 14 the fishing line was oxidized, would it have cracks on 15 the outer layer?</p> <p>16      A. If it's oxidized, it will have cracks on the 17 outer layer.</p> <p>18      Q. And in your fishing line example, would those 19 cracks on the outer layer reduce physical properties of 20 the fishing line?</p> <p>21      A. Cracks can certainly reduce physical 22 properties.</p> <p>23      Q. It would reduce the toughness of the fishing 24 line?</p>
<p style="text-align: center;">Page 67</p> <p>1       A. I cautioned them about use of polypropylene 2 mesh broadly, that the material is degrading, whether 3 it's hernia or pelvic.</p> <p>4       Q. But have you ever told doctors at UT that 5 Prolene mesh should not be used for hernia repair?</p> <p>6       A. Explicitly Prolene by name, no, but when I say 7 "polypropylene mesh," logically that includes the whole 8 range of manufacturers, including Prolene.</p> <p>9       Q. And, Doctor, have you concluded that -- have 10 you ever concluded that Prolene is toxic to the human 11 body?</p> <p>12      A. I have not.</p> <p>13      Q. Doctor, can you tell us the mechanism of action 14 by which oxidation causes pain in the human body?</p> <p>15      A. Yes, I can. Oxidation in polypropylene takes 16 place in the amorphous regions of the polypropylene. 17 Polypropylene is really a composite. It's about half 18 crystals. That's what gives polypropylene its strength.</p> <p>19      Q. Well, I'm going to get to the -- we're actually 20 going to get to that in just a minute. My question is 21 about how the mechanism of action of oxidation causes 22 pain in the human body.</p> <p>23      A. Okay. Oxidation causes the mesh to stiffen. 24 The mesh is designed to be flexible and to move with the</p>	<p style="text-align: center;">Page 69</p> <p>1       A. It would reduce toughness.</p> <p>2       Q. It would reduce the tensile strength of the 3 fishing line?</p> <p>4       A. It would reduce tensile strength if those 5 cracks were large enough.</p> <p>6       Q. Doctor, you know that Ethicon has a long 7 history of use of Prolene sutures, don't you?</p> <p>8       A. Yes.</p> <p>9       Q. Do you know how long the sutures have been on 10 the market?</p> <p>11      A. Many years. Probably around 50 years.</p> <p>12      Q. And do you know if the sutures, Ethicon 13 sutures, were approved by FDA as safe and effective?</p> <p>14      A. I must assume that they were, yes.</p> <p>15      Q. Doctor, do you have any criticisms whatsoever 16 regarding Ethicon's Prolene sutures?</p> <p>17      A. No, I think the sutures are perfectly fine.</p> <p>18      Q. Doctor, is it your testimony that patients -- 19 strike that.</p> <p>20      Doctor, is it your opinion that every doctor 21 who uses a Prolene mesh product for pelvic floor repair 22 is committing malpractice?</p> <p>23      A. No.</p> <p>24      Q. Doctor, what about the surgeons, the implanting</p>

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<p>1   surgeons for these 28 plaintiffs, Ms. Bonnie Blake, all  2   the way down through Ms. Wroble, did these doctors  3   commit malpractice by using a Prolene implant in these  4   plaintiffs?</p> <p>5   A. I don't believe they did. They used a product  6   that Ethicon represented to them was safe for use.</p> <p>7   Q. Doctor, do you know what "the gold standard"  8   means?</p> <p>9   A. I've certainly heard the term.</p> <p>10   Q. Have you ever heard or read that TTVT is known  11   as the gold standard?</p> <p>12   A. I have read that.</p> <p>13   Q. And, Doctor, do you disagree with the doctors  14   and scientists who have called TTVT the gold standard?</p> <p>15   MR. MONSOUR: Objection. Form.</p> <p>16   A. Could you repeat the question?</p> <p>17   Q. Do you disagree with the doctors and scientists  18   who have called TTVT the gold standard?</p> <p>19   MR. MONSOUR: Objection. Form.</p> <p>20   A. They can certainly call it the gold standard.</p> <p>21   That's fine. That's their opinion.</p> <p>22   Q. Do you disagree with that?</p> <p>23   A. I do. I'm an expert in the material that these  24   meshes are made of, and the mesh, in my opinion, is</p>	<p>1   but there's a certain percentage of people that do.  2   Q. Do you know that percentage?</p> <p>3   A. Well, I don't, and I'm not here to guess.</p> <p>4   Q. Okay. Doctor, what would the gold standard be,  5   in your opinion, for the material used to treat pelvic  6   floor repair?</p> <p>7   A. From the literature I've reviewed, it looks  8   like polyvinylidene fluoride might be a better choice.</p> <p>9   Q. PVDF; is that correct?</p> <p>10   A. Yes. It looks like PET might also be a better  11   choice.</p> <p>12   Q. And what does PET stand for?</p> <p>13   A. Polyethylene terephthalate.</p> <p>14   Q. And PVDF is polyvinylidene fluoride; correct?</p> <p>15   A. Yes.</p> <p>16   Q. And, Doctor, is it your testimony that -- which  17   one is -- well, let me back up.</p> <p>18   Are you aware of any other materials that  19   should be used for pelvic floor repair other than PVDF  20   and PET?</p> <p>21   A. I think those are the ones that people have  22   done some studies on and they show some promising  23   results.</p> <p>24   Q. And is it your testimony that PVDF and PET are</p>
<p>1   unsuitable for use in pelvic applications.</p> <p>2   Q. Doctor, is it your opinion that every person  3   who has had a Prolene vaginal mesh implant will  4   experience product failure?</p> <p>5   A. Not everyone will experience product failure.</p> <p>6   People are different. There can be -- you can put the  7   same mesh in two different people and they'll respond  8   differently.</p> <p>9   But what I do believe is, if you leave that  10   mesh in there long enough, you will have oxidative  11   degradation of that mesh occurring, and it will stiffen.</p> <p>12   Q. And that would be for hernia repair too?</p> <p>13   A. Yes.</p> <p>14   Q. Doctor, how can you tell which particular  15   person will have product failure that have received a  16   Prolene vaginal mesh?</p> <p>17   A. I don't know.</p> <p>18   Q. And, Doctor, is it your opinion that every  19   person who has had a Prolene hernia mesh implant will  20   experience product failure?</p> <p>21   A. No.</p> <p>22   Q. Why not?</p> <p>23   A. Well, the record bears it out. A lot of people  24   have these implants and they never experience problems,</p>	<p>1   the safer alternatives than Prolene, Doctor?</p> <p>2   A. They're less susceptible to degradation inside  3   the human body.</p> <p>4   Q. Are they safer alternatives than Prolene,  5   Doctor?</p> <p>6   A. More studies would have to be carried out.</p> <p>7   Q. Can you testify to a reasonable degree of  8   scientific certainty whether or not PVDF and PET are  9   safer alternatives compared to Prolene?</p> <p>10   A. I can only say that they're less susceptible to  11   degradation inside the human body.</p> <p>12   Q. My question, sir, can you testify to a  13   reasonable degree of scientific certainty on whether or  14   not they are safer alternatives compared to Prolene?  15   Yes or no?</p> <p>16   A. No, I'd need more data.</p> <p>17   Q. Doctor, are you aware of any -- and, by the  18   way, which material are you advocating, PVDF or PET?</p> <p>19   A. I'm not really an advocate for any of these  20   materials.</p> <p>21   Q. Which materials do you believe would be safer  22   between PVDF and PET?</p> <p>23   A. I'm not here to testify about that. I'm here  24   to testify that polypropylene, including Prolene, is a</p>

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<p>1 bad choice.</p> <p>2 Q. Do you have an opinion, sir, to a reasonable</p> <p>3 degree of scientific certainty on whether or not PVDF or</p> <p>4 PET is a safer alternative?</p> <p>5 A. I think they're worth investigating.</p> <p>6 Q. Can you make a difference between the two?</p> <p>7 A. No.</p> <p>8 Q. Doctor, are you aware of any medical device on</p> <p>9 the planet that's made out of PVDF for use in vaginal</p> <p>10 reconstructive surgery?</p> <p>11 A. The actual product name? I could go into some</p> <p>12 of these papers and find out. Would you like for me to?</p> <p>13 Q. Yeah, I'd like for you to --</p> <p>14 A. We can go to the Mary, for example.</p> <p>15 Q. My question, sir, are you aware of any mesh,</p> <p>16 vaginal mesh, on the market that is made out of PVDF?</p> <p>17 A. I am not aware of one.</p> <p>18 Q. And, Doctor, you've never tested the</p> <p>19 durability, the tensile strength, or the toughness of</p> <p>20 PVDF or PET, have you?</p> <p>21 A. We have done some testing of PET for sure.</p> <p>22 Q. What about PVDF?</p> <p>23 A. I don't believe we have.</p> <p>24 Q. And, Doctor, would you ever give PVDF a</p>	<p>1 comprised of proteins?</p> <p>2 A. Tissue's certainly got proteins in there.</p> <p>3 Q. And do you know the adhesion properties of PVDF</p> <p>4 compared to Prolene?</p> <p>5 A. I haven't measured those, no.</p> <p>6 Q. Fair to say, based on your chemical background,</p> <p>7 Doctor, that PVDF is a hybrid between polypropylene and</p> <p>8 Teflon?</p> <p>9 A. I would characterize it as more of a hybrid</p> <p>10 between polyethylene and Teflon.</p> <p>11 Q. Nevertheless, it's right in the middle; right?</p> <p>12 A. It's right in the middle, but that one methyl</p> <p>13 group makes a big difference on polypropylene.</p> <p>14 Q. And, Doctor, you've -- strike that.</p> <p>15 You've never designed a PVDF or PET implant of</p> <p>16 any kind; correct?</p> <p>17 A. I have not.</p> <p>18 Q. Doctor, could any mesh product be reasonably</p> <p>19 safe and effective for its intended use in the pelvic</p> <p>20 floor region?</p> <p>21 A. Repeat that, please.</p> <p>22 Q. Could any mesh product be reasonably safe and</p> <p>23 effective for use in the pelvic floor region?</p> <p>24 A. It's certainly possible, yes.</p>
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<p>1 lifetime guarantee if it was implanted in a woman?</p> <p>2 A. I would need some more data before I would do</p> <p>3 that.</p> <p>4 Q. Same for PET?</p> <p>5 A. Yes.</p> <p>6 Q. PVDF is a different chemical composition of</p> <p>7 Prolene; correct?</p> <p>8 A. Yes.</p> <p>9 Q. So is PET?</p> <p>10 A. Yes.</p> <p>11 Q. And you've never done a study to determine</p> <p>12 whether or not PVDF or PET is a safer alternative;</p> <p>13 correct?</p> <p>14 A. I have not.</p> <p>15 Q. And are you aware of any literature that says</p> <p>16 PVDF or PET is a safer alternative than Prolene?</p> <p>17 A. No. As I said earlier, you asked me this</p> <p>18 before, I said that I've seen literature that says</p> <p>19 they're less susceptible to degradation inside the human</p> <p>20 body.</p> <p>21 Q. You've never done a study to determine whether</p> <p>22 or not tissue will adhere to PVDF, have you?</p> <p>23 A. I have not.</p> <p>24 Q. Okay. And you understand that tissue is</p>	<p>1 Q. And could you tell us what that composition</p> <p>2 consists of?</p> <p>3 A. I can tell you what it's not, and that's</p> <p>4 polypropylene.</p> <p>5 Q. Can you tell us what the composition should be,</p> <p>6 sir?</p> <p>7 A. I cannot.</p> <p>8 Q. Can you tell us the thickness?</p> <p>9 A. No.</p> <p>10 Q. Can you tell us the weave?</p> <p>11 A. No.</p> <p>12 Q. Can you tell us the pore size?</p> <p>13 A. No.</p> <p>14 Q. Can you tell us the tensile strength?</p> <p>15 A. No.</p> <p>16 Q. Can you tell us the density?</p> <p>17 A. No.</p> <p>18 Q. Are you aware of anybody who has done a</p> <p>19 design -- strike that.</p> <p>20 Doctor, as a materials scientist, are you aware</p> <p>21 of any material that's completely inert?</p> <p>22 A. No.</p> <p>23 Q. And, Doctor, are you aware of any product on</p> <p>24 the market for treatment of stress urinary incontinence</p>

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1 or pelvic organ prolapse that is completely inert?	1 A. There will be reduction in molecular weight.
2 A. No.	2 And I want to be specific about molecular weight.
3 Q. Doctor, are you aware of any medical device in	3 Molecular weight is a term that gets tossed around
4 the world that is completely inert?	4 loosely a lot with polymers, but there are different
5 A. No.	5 types of average molecular weights.
6 Q. Degradation. How do you define degradation?	6 Q. Right.
7 A. Change in the chemical structure.	7 A. Number average, weight average.
8 Q. And it also means a loss of molecular weight;	8 Q. I'm going to get to those in just a minute.
9 correct?	9 But if oxidation occurs, you must have cleavage of the
10 A. Well, again, we're back to where we were a	10 polymer chain?
11 couple of times previously. Degradation means a change	11 A. Oxidative degradation of polypropylene does
12 in structure. It's detected with spectroscopy as	12 lead to chain cleavage, that's correct.
13 introduction of different chemical groups. It can also	13 Q. And oxidative degradation of Prolene leads to
14 be detected in polymers by degradation, decrease in the	14 strong carbonyl bands present on FTIR that weren't there
15 molecular weight.	15 before; correct?
16 Mechanical properties are a consequence of	16 A. Correct.
17 the -- mechanical properties changes are a consequence	17 Q. And strong -- I'm sorry.
18 of these chemical changes.	18 Oxidative degradation of Prolene leads to
19 Q. Doctor, have you ever testified that	19 reduced physical properties; correct?
20 degradation means loss of molecular weight?	20 A. It changes physical properties. It depends on
21 A. That degradation means loss of molecular	21 the particular one whether it's reduced or not.
22 weight? Degradation of a polymer can certainly be loss	22 Q. And when the polymer chain is cleaved, there's
23 of molecular weight, but you could have oxidative	23 a reduction in physical properties; correct?
24 degradation of a material. In its early stages, you're	24 A. Well, you have to specify which one.
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1 actually increasing the molecular weight because you're	1 Q. All right. My question, sir, is the polymer
2 incorporating oxygen into it.	2 chain of Prolene. When the polymer chain of Prolene is
3 Q. Doctor, there must be a loss of molecular	3 cleaved, there will be a reduction in physical
4 weight for degradation to occur; correct?	4 properties?
5 A. Must be a loss of? Well, with polymers, if	5 A. Again, it's which one? Are you talking about
6 you're talking about oxidative degradation of	6 tensile strength? Are you talking about compliance?
7 polypropylene, you will see a reduction in molecular	7 Are you talking about modules?
8 weight.	8 Q. I'm talking about, actually, any physical
9 Q. Thank you. And there must be -- there must be	9 property.
10 a reduction in molecular weight for degradation for a	10 A. Well, the tensile strength when molecular
11 polymer; correct? You can't have one without the other?	11 weight decreases will generally decrease. Tensile
12 A. Degradation? Yes, you can. You can have	12 strength will decrease. But if you have this oxidative
13 chemical changes. Remember, I defined degradation as	13 degradation occurring in the material, the modulus of
14 chemical changes in the polymer. You could have	14 the material will actually increase, but the compliance
15 oxidation occurring at some level not to the point where	15 decreases.
16 it actually starts to cleave the chain and you will see	16 Q. Will toughness decrease when there's oxidative
17 increase in the molecular weight of the material.	17 degradation?
18 Q. But, Doctor, for oxidative degradation to	18 A. Yes. The material becomes embrittled.
19 occur, there must be loss of molecular weight; correct?	19 Q. And, Doctor, you know what toughness is, don't
20 A. Yes, when oxidative degradation of	20 you?
21 polypropylene occurs, there is degradation of molecular	21 A. I do.
22 weight.	22 Q. And that's the area -- that's the area under
23 Q. And when oxidative degradation of Prolene	23 the curve under a stress-strain?
24 occurs, there must be loss of molecular weight; correct?	24 A. That's one good measure of toughness, yes.

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<p>1       Q. In fact, that's probably the best measure of 2       toughness, isn't it?</p> <p>3       A. It's a great one, yes.</p> <p>4       Q. Okay. And that's the one you teach your 5       students at UT?</p> <p>6       A. I certainly do, yes.</p> <p>7       Q. Okay. And when a material increases in 8       toughness, what does that tell you about the property, 9       physical properties?</p> <p>10      A. It tells me it got tougher.</p> <p>11      Q. And when a material increases in toughness, 12     what does that tell you about whether or not degradation 13     has occurred?</p> <p>14      A. It would -- it might depend on the material. 15     You can't just make a broad, sweeping statement with 16     every material that it's going to be the same.</p> <p>17      Q. Okay. What about Prolene? What does that tell 18     you about the toughness of Prolene?</p> <p>19      A. It's known that when polypropylene oxidatively 20     degrades, it becomes embrittled. So less tough, more 21     brittle.</p> <p>22      Q. And for Prolene, when -- if Prolene oxidatively 23     degrades, Prolene toughness will decrease; correct?</p> <p>24      A. Yes.</p>	<p>1       Q. No, sir. My question is: Are you aware of any 2       peer-reviewed literature that shows Prolene has lost 3       molecular weight?</p> <p>4       A. You mean it's become lower molecular weight 5       after a degradation process?</p> <p>6       Q. My question is: Are you aware of any 7       peer-reviewed literature that shows Prolene has lost 8       molecular weight specifically?</p> <p>9       A. Has lost molecular weight due to what? That's 10      what I'm asking.</p> <p>11      Q. For any reason.</p> <p>12      A. If one just takes the material and puts it in 13     an extruder and keeps heating and shearing it, it's 14     going to lose molecular weight.</p> <p>15      Q. Right. But my question is about peer-reviewed 16     literature. Are you aware of any peer-reviewed 17     literature that shows Prolene has lost molecular weight 18     specifically?</p> <p>19      A. As I sit here, I don't know a paper with 20     Prolene specifically.</p> <p>21      Q. And are you aware of any studies that shows 22     Prolene has lost molecular weight?</p> <p>23      A. Again, your question is vague and I don't 24     understand your question.</p>
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<p>1       Q. Do you know Dr. Howard Jordi?</p> <p>2       A. I've heard the name. I don't know him.</p> <p>3       Q. Do you know if he has ever found a loss of 4       molecular weight in an explant?</p> <p>5       A. I don't know.</p> <p>6       Q. We talked about this earlier, and if we did, I 7       apologize. If there is a loss of molecular weight, 8       there is a decrease in toughness; correct? Of Prolene?</p> <p>9       A. A decrease in molecular weight?</p> <p>10      Q. If there's a loss of molecular weight in 11     Prolene, there's a decrease in toughness of Prolene; 12     correct?</p> <p>13      A. Yes, there generally would be a decrease in 14     toughness with decrease in molecular weight, but it's 15     not that simple, because people have tried with 16     ultrahigh molecular weight polymers like polyethylene to 17     get the degree of crystallinity as high as possible 18     through processing tricks, and if you do that, you can 19     actually cause the material to become brittle. So 20     processing plays a role. I'm not trying to be 21     difficult. It's just -- it's more complicated.</p> <p>22      Q. Doctor, are you aware of any peer-reviewed 23     literature that shows Prolene has lost molecular weight?</p> <p>24      A. You mean has actually been degraded?</p>	<p>1       Q. My question is, sir: Are you aware of any 2       studies that shows Prolene has specifically lost 3       molecular weight?</p> <p>4       A. It has become reduced in molecular weight, one 5       average or the other, after some physical encounter? As 6       I sit here, no.</p> <p>7       Q. And, Doctor, have you ever seen any type of 8       specific molecular weight tests that have been done on 9       Prolene?</p> <p>10      A. I saw a little bit of GPC data in some of the 11     internal Ethicon documents.</p> <p>12      Q. And what did it show?</p> <p>13      A. What they showed in that limited data was 14     marginal changes, small changes, in molecular weight.</p> <p>15      Q. Doctor, are you aware of any evidence to 16     confirm that these 28 plaintiffs' explants lost 17     molecular weight?</p> <p>18      A. I have not seen molecular weight data on 19     explants of these patients.</p> <p>20      Q. And, Doctor, have you seen any evidence to 21     confirm that these 28 patients' explants had a change in 22     the physical properties of their mesh?</p> <p>23      A. Just back to what I said earlier, 24     polypropylene, including Prolene, undergoes oxidative</p>

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<p>1 degradation.</p> <p>2 Q. Doctor, we've talked about antioxidants</p> <p>3 already?</p> <p>4 A. Yes.</p> <p>5 Q. Do you know the antioxidants that are added to</p> <p>6 turn pure polypropylene into Prolene?</p> <p>7 A. Yes. There's several additives that are put in</p> <p>8 there. I've actually got a document here that lists the</p> <p>9 amounts of all of them, but there's Santonox, the</p> <p>10 primary antioxidant, there's calcium stearate, a</p> <p>11 processing aid, and there's a secondary antioxidant. I</p> <p>12 forget the name. It's a long, complicated name. You</p> <p>13 probably wouldn't want to type it.</p> <p>14 Q. Dilauryl thiodipropionate?</p> <p>15 A. That's it. That's it.</p> <p>16 Q. Doctor, do you know the concentration levels of</p> <p>17 these antioxidants?</p> <p>18 A. Again, I would have to --</p> <p>19 Q. Excuse me -- that are -- do you know the</p> <p>20 concentration levels of these antioxidants that are</p> <p>21 added to make polypropylene Prolene?</p> <p>22 A. I could go and review it, but I can't off the</p> <p>23 top of my head remember the exact amount.</p> <p>24 Q. Doctor, have you ever done a TGA analysis to</p>	<p>1 A. No.</p> <p>2 Q. And you've never studied how long the</p> <p>3 antioxidants in Prolene will delay oxidation in vivo;</p> <p>4 correct?</p> <p>5 A. I've seen literature both internal to Ethicon</p> <p>6 and peer-reviewed literature that shows degradation of</p> <p>7 Prolene biomaterials after certain times of implantation</p> <p>8 in the body, but I haven't tested it with my own hands.</p> <p>9 Q. And, Doctor, do you know the step in the</p> <p>10 manufacturing process where these antioxidants are</p> <p>11 added?</p> <p>12 A. Yes. It's during the extrusion process. These</p> <p>13 pellets basically are produced by that process.</p> <p>14 Q. It's your testimony under oath that the pellets</p> <p>15 are produced during the extrusion process?</p> <p>16 A. Well, the polypropylene comes out of the</p> <p>17 reactor, and as I understand it, they then are</p> <p>18 introducing the antioxidant into the material by a</p> <p>19 mixing process, basically.</p> <p>20 Q. So my question is: At what stage of the</p> <p>21 manufacturing process are the antioxidants added?</p> <p>22 A. It's put in before the fibers are actually</p> <p>23 spun. It's in there in the polypropylene.</p> <p>24 Q. Is it put -- is it put before the fibers are</p>
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<p>1 determine what antioxidants Prolene contains?</p> <p>2 A. I have not performed TGA on Prolene.</p> <p>3 Q. And, Doctor, have you ever done any type of TGA</p> <p>4 analysis to determine whether or not antioxidants had</p> <p>5 been depleted from Prolene?</p> <p>6 A. I have not.</p> <p>7 Q. You did that for Boston Scientific, didn't you?</p> <p>8 A. Yes.</p> <p>9 Q. Why didn't you do it here?</p> <p>10 A. Because I didn't have the explants.</p> <p>11 Q. That could have been -- you could have done</p> <p>12 that by other means; correct?</p> <p>13 A. One could use an oxidation induction test.</p> <p>14 That's an alternate way.</p> <p>15 Q. And that's something that you had available to</p> <p>16 your lab at Tennessee?</p> <p>17 A. We did, yeah. We could have done that.</p> <p>18 Q. And that's something you didn't do in this</p> <p>19 case; correct?</p> <p>20 A. We didn't.</p> <p>21 Q. Doctor, you've never tested the effect of</p> <p>22 antioxidants -- strike that.</p> <p>23 You've never tested the effect antioxidants</p> <p>24 have in vivo in Ethicon's Prolene, have you?</p>	<p>1 extruded?</p> <p>2 A. Yes, it's in there before the fibers are</p> <p>3 extruded.</p> <p>4 Q. Doctor, you'll agree that these antioxidants</p> <p>5 work in a synergistic manner; correct?</p> <p>6 A. You mean the two that are in? Yeah, it's</p> <p>7 common to use primary and secondary antioxidants.</p> <p>8 Q. But they work in a synergistic manner?</p> <p>9 A. Yes, they do.</p> <p>10 Q. Okay. And, Doctor, do you know the rate at</p> <p>11 which antioxidants from Prolene are depleted?</p> <p>12 A. Based on the literature that shows the</p> <p>13 oxidation of the material, you can certainly tell when</p> <p>14 depletion has occurred, because that's when you start to</p> <p>15 see signs of oxidative degradation.</p> <p>16 Q. Right, but I'm talking about, Doctor, the rate</p> <p>17 that antioxidants of Prolene are depleted.</p> <p>18 A. Under what conditions?</p> <p>19 Q. In vivo.</p> <p>20 A. The exact rate, some actual study of what's</p> <p>21 happening to the concentration over time, I'm not aware</p> <p>22 of.</p> <p>23 Q. And, Doctor, you're not aware of any</p> <p>24 peer-reviewed literature that shows the rate the</p>

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<p>1 antioxidants are depleted, are you, in Prolene?</p> <p>2 A. The direct measure of the depletion at the</p> <p>3 surface, which is where the antioxidant does its work,</p> <p>4 I'm not aware of that exact data, that's correct.</p> <p>5 Q. And, Doctor, you've never done any -- you've</p> <p>6 never done any time studies to determine the rate at</p> <p>7 which the antioxidants of Prolene are depleted, have</p> <p>8 you?</p> <p>9 A. We have not tested Prolene for that.</p> <p>10 Q. Doctor, I didn't see anything in your report</p> <p>11 about leaching, or did I miss it?</p> <p>12 A. I did not have anything in there about</p> <p>13 leaching.</p> <p>14 Q. Okay. And if you don't have anything in your</p> <p>15 report, is it fair for me to assume that you have no</p> <p>16 opinions regarding leaching of antioxidants; correct?</p> <p>17 A. Well, certainly antioxidants can be leached out</p> <p>18 of a material.</p> <p>19 Q. But my question is, sir: Are you testifying to</p> <p>20 a reasonable degree of scientific certainty in this</p> <p>21 litigation on whether or not the antioxidants can leach</p> <p>22 out of Prolene?</p> <p>23 A. Antioxidants on the surface can leach out.</p> <p>24 Q. And is that included in your -- is that opinion</p>	<p>1 A. I believe it would, yes.</p> <p>2 Q. And, in fact, formalin is a good solvent;</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. Doctor, do you have any evidence that these 28</p> <p>6 plaintiffs had a loss of antioxidants in their mesh?</p> <p>7 Any data to confirm that their explants lost</p> <p>8 antioxidants?</p> <p>9 A. When you put a material inside the human body,</p> <p>10 you get the foreign body response, and that generates</p> <p>11 strong oxidizing agents, and those oxidizing agents use</p> <p>12 up the antioxidant. The antioxidant's put in there to</p> <p>13 preferentially react with oxidizing species and with</p> <p>14 free radicals.</p> <p>15 Q. Doctor, can you tell us how any of these 28</p> <p>16 plaintiffs' antioxidants -- strike that.</p> <p>17 Can you tell us how any -- strike that.</p> <p>18 Can you tell us the rate at which the</p> <p>19 antioxidants of any of these 28 plaintiffs were</p> <p>20 depleted?</p> <p>21 A. The exact rate, no.</p> <p>22 MR. HUTCHINSON: Can we take a quick break?</p> <p>23 MR. MONSOUR: Yes.</p> <p>24 (Recess from 10:20 a.m. until 10:35 a.m.)</p>
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<p>1 included in your report?</p> <p>2 A. No, but we talk about how the antioxidants are</p> <p>3 depleted over time.</p> <p>4 Q. Why are none of your leaching -- strike that.</p> <p>5 Why are none of your opinions regarding</p> <p>6 leaching included in your expert report?</p> <p>7 A. I think leaching is a relatively minor cause of</p> <p>8 depletion as opposed to the antioxidants simply being</p> <p>9 used up doing their job.</p> <p>10 Q. Doctor, my question is: Why did you not</p> <p>11 include any opinions regarding leaching in your expert</p> <p>12 report?</p> <p>13 A. I don't think they're really relevant here.</p> <p>14 The oxidizing agents inside the body react with the</p> <p>15 antioxidants on the surface of the fiber, and that's the</p> <p>16 primary cause for depletion of the antioxidants, and</p> <p>17 then the subsequent oxidative degradation process.</p> <p>18 Q. As a polymer scientist, you're familiar with</p> <p>19 formalin; correct?</p> <p>20 A. Yes.</p> <p>21 Q. And you know that formalin extracts Santonox R;</p> <p>22 correct?</p> <p>23 A. Yes.</p> <p>24 Q. And you know formalin extracts DLTDP; correct?</p>	<p>1 MR. HUTCHINSON: Back on the record.</p> <p>2 BY MR. HUTCHINSON:</p> <p>3 Q. Doctor, is there anything about the testimony</p> <p>4 you've given me you'd like to change?</p> <p>5 A. No.</p> <p>6 Q. Let's look at the expert report, Exhibit 3.</p> <p>7 A. Okay.</p> <p>8 Q. Page 2. Middle paragraph. It states you have</p> <p>9 developed new biomaterials?</p> <p>10 A. Yes.</p> <p>11 Q. Are they sold to anyone right now, sir?</p> <p>12 A. No. We've got a patent on a new orthopedic</p> <p>13 bone cement.</p> <p>14 Q. Do they have a lifetime warranty?</p> <p>15 A. Well, as I say, we haven't actually made the</p> <p>16 product, but --</p> <p>17 Q. You haven't made the product?</p> <p>18 A. We haven't made the commercial product.</p> <p>19 Q. Okay. Well, but will this commercial product</p> <p>20 have a lifetime warranty?</p> <p>21 A. I don't know.</p> <p>22 Q. Will it have any warranty at all?</p> <p>23 A. I don't know.</p> <p>24 Q. And it's a biomaterial product?</p>

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<p>1       A. It's a biomaterial.      2       Q. And what's it used for?      3       A. It would be used for hip replacement surgeries,      4       knees.      5       Q. And sitting here today, sir, do you have any      6       plans to give this hip implant that you're creating a      7       lifetime warranty?      8       A. I have no plans one way or the other.      9       Q. You only have one patent; correct?      10      A. No.      11      Q. I'm looking at the top of page 3. It says "a      12     patent," which I think is singular. How many patents do      13     you have?      14      A. There's a list in here. If you go to my CV,      15     it's after the publications. There's a list of patents.      16     There's several issued patents there and there's a total      17     of 17 things listed in various stages. It's right after      18     the publications but before the presentations start.      19       MR. MONSOUR: Maybe next time we ought to      20     number at the bottom to make it easier. This is      21     pretty long.      22       THE WITNESS: That would make it easier.      23     BY MR. HUTCHINSON:      24       Q. Doctor, none of those patents have anything to</p>	<p>1       oxidize? What do you mean by "foreign body material"?      2       Do you mean something that's being implanted in the      3       human body?      4       Q. Yes.      5       A. Maybe Teflon.      6       Q. You said "maybe." You don't sound too sure.      7       A. I'm not sure. The human body is pretty      8       aggressive.      9       Q. Yeah. And, in fact, Doctor, sitting here      10      today, can you tell us the name of one medical product      11      commercially available that will never oxidize in the      12      human body?      13      A. No.      14      Q. Doctor, turning to page 5, at the top, you      15      state: "This report focuses on" -- do you see that?      16      A. Yes.      17      Q. -- "degradation of polypropylene by      18      thermo-oxidative processes."      19       What do you mean by "thermo"?      20      A. Combination of heat combined with oxygen.      21      Q. And are you talking about a process of heat      22      initiated in the body?      23      A. No, it's degradation of polypropylene by      24      thermo-oxidative processes and in vivo. So they're two</p>
<p style="text-align: center;">Page 95</p> <p>1       do with pelvic mesh; correct?      2       A. Correct.      3       Q. And, Doctor, looking at the top of page 3, it      4       says: "My work." Are you there with me?      5       A. Yes.      6       Q. "My work in this area includes development of      7       novel bone cements, dental biomaterials, tissue      8       engineering, drug delivery systems, surgical sealants,      9       and polypropylene pelvic mesh."      10      Did I read that correctly?      11      A. Yes.      12      Q. And, Doctor, what development of polypropylene      13      pelvic mesh have you done?      14      A. Well, actually, I was referring to the study      15      that we did on the materials.      16      Q. Okay. So you've never developed polypropylene      17      pelvic mesh, have you, sir?      18      A. No, not actually developed it.      19      Q. Is that a little misleading?      20      A. Yeah, I probably was a little clumsy in terms      21      of how I phrased it.      22      Q. Doctor, are you aware of any foreign body      23      material that will never oxidize?      24      A. Any foreign body material which will never</p>	<p style="text-align: center;">Page 97</p> <p>1       separate things.      2       Q. Doctor, you're not telling the ladies and      3       gentlemen of the jury that Prolene oxidizes via thermal      4       means; correct?      5       A. Well, polypropylene is susceptible to thermal      6       oxidative degradation. You heat Prolene up in the      7       presence of oxygen and it will degrade.      8       Q. Right. But, Doctor, are you offering any      9       opinions on Prolene oxidizing in the human body as a      10      result of high temperatures?      11      A. Not high temperature. In the body, it's      12      obviously at body temperature, 37 degrees.      13      Q. And, Doctor, have you proven using the      14      scientific method that Prolene oxidizes in the body at      15      37 degrees C?      16      A. We've proven that polypropylene oxidizes inside      17      the body at 37 degrees C.      18      Q. I understand.      19      A. And Ethicon's own scientists have shown that      20      polypropylene oxidizes in vivo.      21      Q. My question to you, Doctor, is: Have you      22      personally proven using the scientific method that      23      Prolene oxidizes in vivo at 37 degrees C?      24      A. I have not done the experiment with</p>

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<p>1 polypropylene, but as I say, the Ethicon people have,      2 and others have looked at degradation of Prolene      3 implants inside the body.</p> <p>4 Q. Doctor, turning to page 5, under summary of      5 opinions, No. 1, it discusses the chain scission and      6 diminished mechanical properties, reduced compliance and      7 brittleness. Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And as a polymer scientist, you know what solid      10 scientific data is, don't you?</p> <p>11 A. Yes.</p> <p>12 Q. In fact, you use that in your practice?</p> <p>13 A. Yes.</p> <p>14 Q. And using good scientific, solid data is good      15 science; right?</p> <p>16 A. Yes.</p> <p>17 Q. And, Doctor, are you aware of any solid      18 scientific data that shows where Prolene has diminished      19 physical properties?</p> <p>20 A. Yes.</p> <p>21 Q. What?</p> <p>22 A. It would be the papers of Costello.</p> <p>23 Q. Anyone else?</p> <p>24 A. Those are the primary ones that have looked at</p>	<p>1 A. I am in that document, yes.</p> <p>2 Q. And, Doctor, you'll agree that only one      3 explanted fiber was tested, would you not?</p> <p>4 A. It was 5-0 Prolene from Specimen 2.</p> <p>5 Q. But one explanted fiber was tested; correct?</p> <p>6 A. They performed tests on one explanted fiber,      7 but there's no indication of how many times that might      8 have been tested.</p> <p>9 Q. And, Doctor, as a scientist, would you ever      10 rely on one data point in drawing conclusions for a      11 paper that you'd present to the American Chemical      12 Society?</p> <p>13 A. Well, my point is, they may have actually      14 tested that sample multiple times.</p> <p>15 Q. But my question to you, Doctor, and listen      16 closely to my question: Would you ever rely, as a      17 scientist, on one data point in drawing a conclusion for      18 a paper that you'd present to the American Chemical      19 Society?</p> <p>20 A. I would rely on one data point, but I would      21 want more data, and what they show in this paper is      22 there's evidence of other fibers cracking.</p> <p>23 Q. And, Doctor, did you rule out that the fiber      24 had been damaged by a scalpel? Did you rule that out?</p>
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<p>1 Prolene.</p> <p>2 Q. Right. But, Doctor, I'm asking you for solid      3 scientific data. Other than Costello, are you aware of      4 any solid scientific data that shows Prolene has      5 diminished physical properties?</p> <p>6 A. There's also data in Ethicon's own studies      7 where in one instance material retained only 54 percent      8 of its initial strength after oxidative degradation.</p> <p>9 Q. Doctor, you're talking about the 1983 document      10 from Ethicon?</p> <p>11 A. I'd have to look at it. There's a couple of      12 1983 documents, but that sounds about right.</p> <p>13 Q. But when we're talking about the suture      14 retained only 54 percent of its original strength,      15 you'll agree that in that study only one explanted fiber      16 was tested?</p> <p>17 A. I'd have to look at that study to say.</p> <p>18 Q. Okay. Do you have that study with you?</p> <p>19 A. I believe I do.</p> <p>20 What was the number on that one? I'd have to      21 go back to my report and track it down that way.</p> <p>22 Q. ETH.MESH.15955438?</p> <p>23 A. Okay.</p> <p>24 Q. Are you there with me, Doctor?</p>	<p>1 A. You would think that they would not test      2 material that had been damaged by a scalpel.</p> <p>3 Q. How did you rule that out?</p> <p>4 A. I don't have the fiber to examine.</p> <p>5 Q. And you didn't rule that out that the fiber had      6 been damaged by a scalpel, had you?</p> <p>7 A. Well, I trust that Ethicon hires good      8 scientists who would be careful.</p> <p>9 Q. Did you rule out the fact that Ethicon's fiber      10 was damaged by a scalpel?</p> <p>11 A. I have no evidence that it was.</p> <p>12 Q. If you look at -- going back to your report, on      13 page 5, where we discussed chain scission, chain      14 scission produces carbonyl bands; correct?</p> <p>15 A. Chain scission in polypropylene accompanies the      16 formation of carbonyl bands. It's not that chain      17 scission produces it, but --</p> <p>18 Q. And chain scission in Prolene accompanies the      19 formulation of carbonyl bands; correct?</p> <p>20 A. Yes.</p> <p>21 Q. In fact, Doctor, a carbonyl band from oxidation      22 is one of the most intensely absorbing functional groups      23 on FTIR; correct?</p> <p>24 A. Yes, it's one that's easy to see.</p>

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<p>1 Q. You can't miss it if there's oxidation; is that 2 right?</p> <p>3 A. If there's oxidation, you'll see it, yes.</p> <p>4 Q. And, in fact, it's a strong and tall peak on 5 the FTIR spectra; correct?</p> <p>6 A. Yes.</p> <p>7 Q. And do you know where oxidized -- strike that. 8 Do you know where on the reciprocal centimeter 9 range there would be a peak for oxidized Prolene?</p> <p>10 A. Yeah, there's several different oxidized 11 species, but you see them, in general, around 1750, 12 roughly.</p> <p>13 Q. And, Doctor, have you ever seen any literature 14 that confirms there's a peak at 1740 reciprocal 15 centimeters for oxidized Prolene?</p> <p>16 A. Yes.</p> <p>17 Q. And what paper is that?</p> <p>18 A. Well, it's certainly there in the documents of 19 Ethicon, but I believe it's there also in the Costello 20 paper.</p> <p>21 Q. Are you aware of any other peer-reviewed 22 literature other than Costello that confirms there's a 23 peak at 1750 reciprocal centimeters for oxidized 24 Prolene?</p>	<p>1 A. Yes.</p> <p>2 Q. In fact, that was something easy for you to do; 3 correct?</p> <p>4 A. It is easy, yes.</p> <p>5 Q. In fact, that's something you could have done; 6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. Are you an expert in FTIR?</p> <p>9 A. I would say I'm quite experienced with it. We 10 use it routinely to characterize polymers that we've 11 made.</p> <p>12 Q. But do you hold yourself as an expert in FTIR?</p> <p>13 A. Well, I'm not a person who's specialized in 14 spectroscopy my whole career, but we use it as a tool 15 routinely.</p> <p>16 Q. Doctor, do you tell the students you teach at 17 UT that you're an expert in FTIR analysis?</p> <p>18 A. I wouldn't classify myself as an expert. 19 There's certainly people that practice it day in and day 20 out that know more about it than I do.</p> <p>21 Q. And, Doctor, do you know -- well, by the way, 22 FTIR is a way to confirm oxidation?</p> <p>23 A. Yes.</p> <p>24 Q. And do you know where on an FTIR spectra a</p>
<p style="text-align: center;">Page 103</p> <p>1 A. For oxidized Prolene, I think that's the one.</p> <p>2 Q. Costello is the one you're relying on?</p> <p>3 A. Yeah. There's actually two Costello papers, 4 yeah.</p> <p>5 Q. Doctor, have you ever seen carbonyl bands from 6 Prolene after it was implanted in vivo?</p> <p>7 A. Well, as we just said, I've seen evidence 8 gathered by Ethicon scientists and also from Costello.</p> <p>9 Q. But outside of the documents that you've 10 reviewed, the internal documents and peer-reviewed 11 literature, Doctor, have you ever seen an FTIR spectra 12 that has a carbonyl band at or around 1750 for oxidized 13 Prolene?</p> <p>14 A. You mean with my -- something we generated in 15 the lab?</p> <p>16 Q. Yes, sir.</p> <p>17 A. No.</p> <p>18 Q. With your own eyes.</p> <p>19 A. No, we have not.</p> <p>20 Q. And, Doctor, have you ever done an FTIR spectra 21 for Prolene?</p> <p>22 A. For polypropylene, yes. For Prolene, no.</p> <p>23 Q. Doctor, you had the equipment at your lab at UT 24 to do an FTIR spectra on Prolene, didn't you?</p>	<p style="text-align: center;">Page 105</p> <p>1 functional group for DLTDP shows up?</p> <p>2 A. There's one that comes in about 1740, in that 3 general vicinity, as well.</p> <p>4 Q. Doctor, looking on page 5 of your report, it 5 says, No. 2: "The addition of antioxidants to the 6 Prolene polypropylene does not permanently prevent mesh 7 degradation."</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. Doctor, have you proven that using the 11 scientific method?</p> <p>12 A. Well, polypropylene routinely contains 13 antioxidants.</p> <p>14 Q. But I'm talking about Prolene. Have you 15 proven, Doctor, that the addition of antioxidants to 16 Prolene does not permanently prevent mesh degradation, 17 by the scientific method?</p> <p>18 A. It's there in the published peer-reviewed 19 literature and also in the Ethicon documents. As I keep 20 saying, we have not done the experiments on Prolene.</p> <p>21 Q. Doctor, what's the longest time that you're 22 aware of where Prolene material has been used in the 23 body?</p> <p>24 A. There were some seven-year studies I saw from</p>

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<p>1 Ethicon.</p> <p>2 Q. I'm talking about used in the body in a 3 clinical sense.</p> <p>4 A. I'd have to go back to some of the papers to 5 see, really, what the longest time was, but periods of 6 years.</p> <p>7 Q. Doctor, look at page 11 for me, please. Down 8 at the middle, you have a sentence regarding -- that 9 starts with "macrophages." Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. Doctor, do you know what amount of peroxides 12 are secreted in the body?</p> <p>13 A. I don't know the exact amount.</p> <p>14 Q. Do you know the amount of acids that are 15 secreted in the body?</p> <p>16 A. Exact amounts, no.</p> <p>17 Q. What about the amount of enzymes?</p> <p>18 A. Exact amounts, no.</p> <p>19 Q. Doctor, have you ever studied the amount of 20 peroxides, acids, or enzymes that are secreted in the 21 body?</p> <p>22 A. I have not.</p> <p>23 Q. Can you quantify the concentration of reactive 24 oxygen species produced by microphages?</p>	<p>1 acids, or enzymes to determine if it oxidizes?</p> <p>2 A. I have not.</p> <p>3 Q. Doctor, the amount of reactive oxygen species 4 in the body, how does that compare to 30 percent 5 hydrogen peroxide?</p> <p>6 A. I'm not sure.</p> <p>7 Q. Certainly, Doctor, you would expect that the 8 amount of reactive oxygen species in the body is going 9 to be much lower than 30 percent hydrogen peroxide, 10 wouldn't you?</p> <p>11 A. 30 percent hydrogen peroxide is a pretty high 12 concentration.</p> <p>13 Q. And that's a high enough concentration that you 14 would expect something to happen to a material; correct?</p> <p>15 A. It depends on the material and the conditions 16 under which it's exposed. If you look inside the human 17 body, you have not only hydrogen peroxide being 18 generated by this foreign body reaction, but you also 19 have oxidative enzymes. So catalysts can accelerate the 20 process even if the concentration of the peroxide is 21 lower. And there are also other highly reactive 22 species, like hypochlorous acid, that are generated by 23 this process.</p> <p>24 Q. And, Doctor, do you have any idea how much</p>
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<p>1 A. It might be available in the literature if I 2 would go and look for it. I suspect it is.</p> <p>3 Q. Can you quantify it, Doctor?</p> <p>4 A. As I sit here, no.</p> <p>5 Q. Have you ever looked for any type of 6 quantification of reactive oxygen species produced by 7 macrophages?</p> <p>8 A. I have not tried to quantify it, no.</p> <p>9 Q. Doctor, are you aware, sitting here today, of 10 any peer-reviewed literature where that's been 11 quantified?</p> <p>12 A. I am not, as I sit here, but it may very well 13 be there. I suspect it is.</p> <p>14 Q. And when we talk about the concentration of 15 reactive oxygen species produced by macrophages, you'd 16 be guessing at the amount of how much is produced by the 17 body; correct?</p> <p>18 A. As I've said, I don't know the exact amount.</p> <p>19 Q. Okay. Do you have -- do you have any idea?</p> <p>20 A. I can't give you a hard number, no.</p> <p>21 Q. Can you give me a best guess?</p> <p>22 A. I'm not here to guess.</p> <p>23 Q. Doctor, have you ever exposed Prolene to what 24 you would consider an appropriate amount of peroxides,</p>	<p>1 hypochlorous acid is found in the body in vivo?</p> <p>2 A. I can't quantify it.</p> <p>3 Q. And, Doctor, are you aware of any literature 4 whatsoever that quantifies the amount of hypochlorous 5 acid in the body?</p> <p>6 A. As I sit here, I'm not sure of it, but I might 7 be able to quantify it.</p> <p>8 Q. Have you ever looked for any literature, 9 Doctor, before today's deposition, that quantifies the 10 amount of hypochlorous acid found in the body?</p> <p>11 A. I have not set out to try to quantify it.</p> <p>12 Q. And have you ever looked in the literature to 13 determine how much hydrogen peroxide is found in the 14 body, the concentration level?</p> <p>15 A. Again, as I've already said, I haven't tried to 16 quantify it.</p> <p>17 Q. Thank you. And, Doctor, these reactive oxygen 18 species that you're discussing on page 11 of your 19 report, are those stronger than nitric acid?</p> <p>20 A. Certainly under the conditions where there are 21 these enzymes present, these oxidative enzymes, they can 22 be very potent.</p> <p>23 Q. Doctor, do you have any opinion regarding how 24 much hydrogen peroxide would cause Prolene to oxidize?</p>

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<p>1 A. Inside the body, or without?</p> <p>2 Q. Inside the body.</p> <p>3 A. I'm not sure what the minimum level is.</p> <p>4 Q. Do you have any opinion regarding how much</p> <p>5 hydrogen peroxide would cause Prolene to oxidize outside</p> <p>6 the body?</p> <p>7 A. Well, I could go to the study that the Ethicon</p> <p>8 scientists carried out.</p> <p>9 Q. Before we do that, do you have an opinion?</p> <p>10 A. Could you be more specific?</p> <p>11 Q. Well, do you have an opinion about how much</p> <p>12 hydrogen peroxide it takes to oxidize Prolene outside</p> <p>13 the body?</p> <p>14 A. It depends on the exact conditions. 30 percent</p> <p>15 hydrogen peroxide, under the conditions Ethicon used,</p> <p>16 wasn't enough.</p> <p>17 Q. It was not enough?</p> <p>18 A. Over the time period that they carried out the</p> <p>19 experiment.</p> <p>20 Q. And you're talking about the November 5, 1984,</p> <p>21 memo?</p> <p>22 A. Yes, I think so.</p> <p>23 (Mays Exhibit No. 4 was marked for</p> <p>24 identification.)</p>	<p>1 the laboratory, but it's hydrogen peroxide and other</p> <p>2 oxidizing agents generated in vivo where there's also</p> <p>3 oxidative enzymes present.</p> <p>4 In fact, if we continue on page 3 to the next</p> <p>5 paragraph in this same article, it says: "Infrared</p> <p>6 spectroscopic examination of Prolene explants, however,</p> <p>7 do show the presence of oxidative end products. While</p> <p>8 the combination of a proportionally small but severely</p> <p>9 oxidized surface and" --</p> <p>10 Q. Doctor, I'm not going to --</p> <p>11 MR. MONSOUR: Let him finish.</p> <p>12 A. -- yeah -- "a small but severely oxidized</p> <p>13 surface and an unaffected core has not been duplicated</p> <p>14 in laboratory oxidation studies, the possibility of a</p> <p>15 highly specific in vivo oxidation process remains. The</p> <p>16 kinetic features of such a process may deviate from</p> <p>17 conventional oxidation and would be difficult to predict</p> <p>18 or duplicate in an artificial environment."</p> <p>19 Q. Doctor, my question to you is: Is hydrogen</p> <p>20 peroxide in a lab different than hydrogen peroxide in</p> <p>21 the body?</p> <p>22 A. Yes, because inside the body it's not just</p> <p>23 hydrogen peroxide.</p> <p>24 Q. I understand that, but --</p>
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<p>1 BY MR. HUTCHINSON:</p> <p>2 Q. We'll mark it as Exhibit 4. This is a document</p> <p>3 that you received before you rendered your opinions; is</p> <p>4 that right?</p> <p>5 A. Yes.</p> <p>6 Q. And, in fact, you relied upon this document in</p> <p>7 reaching your opinions, didn't you, sir?</p> <p>8 A. Yes.</p> <p>9 Q. And there at the top, on page 3, it states:</p> <p>10 "Prolene sutures in 30 percent hydrogen peroxide</p> <p>11 solution after a year's time at room temperature do not</p> <p>12 produce visible surface cracking on any of the fibers."</p> <p>13 Did I read that correctly?</p> <p>14 A. Yes.</p> <p>15 Q. And, in fact, Doctor, this shows that Prolene</p> <p>16 is exposed to 30 percent hydrogen peroxide for a year</p> <p>17 and didn't produce visible surface cracks; is that</p> <p>18 right?</p> <p>19 A. That's what it says.</p> <p>20 Q. Sir, how do you account for the fact -- strike</p> <p>21 that.</p> <p>22 How do you account for that in reaching your</p> <p>23 conclusion that hydrogen peroxide oxidizes Prolene?</p> <p>24 A. As I said before, it's not hydrogen peroxide in</p>	<p>1 A. It's other things.</p> <p>2 Q. Let's focus on hydrogen peroxide first.</p> <p>3 A. Yes, sir.</p> <p>4 Q. Hydrogen peroxide is hydrogen peroxide is</p> <p>5 hydrogen peroxide, regardless of the environment;</p> <p>6 correct?</p> <p>7 A. H<sub>2</sub>O<sub>2</sub>, yes.</p> <p>8 Q. Thank you. Doctor, can you explain why the</p> <p>9 30 percent hydrogen peroxide ate away the cap of the</p> <p>10 vial?</p> <p>11 A. It was a material that was more susceptible to</p> <p>12 degradation.</p> <p>13 Q. And, Doctor, the cap of the vial was Bakelite;</p> <p>14 correct? Top paragraph.</p> <p>15 A. Yes.</p> <p>16 Q. And, Doctor, do you know what Bakelite --</p> <p>17 strike that.</p> <p>18 Do you know what a Bakelite cap is made of?</p> <p>19 A. I think it's some sort of phenolic resin, is it</p> <p>20 not?</p> <p>21 Q. And, Doctor, can you explain why the hydrogen</p> <p>22 peroxide solution ate away the cap of the vial but did</p> <p>23 not produce visible cracks in the Prolene?</p> <p>24 A. Because it's chemically different and it's a</p>

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<p>1 material that's even more susceptible to oxidative 2 degradation by hydrogen peroxide than is the Prolene. 3 Q. And, Doctor, let's look at page 11. 4 MR. MONSOUR: Of the report or of the document? 5 MR. HUTCHINSON: I'm sorry. Of the report. My 6 bad. 7 Q. You write in the third paragraph: "Degradation 8 starts at the surface of the implant where it's in 9 contact with its surroundings." 10 Do you see that? 11 A. Where are we now? 12 Q. Page 11. Third paragraph. Or, actually, it's 13 the first paragraph under "effect of polypropylene 14 degradation." 15 A. I see it, uh-huh. 16 Q. And, Doctor, you write: "Degradation starts at 17 the surface of the implant." 18 Do you see that? 19 A. Yes. 20 Q. And if this occurs with Prolene, you would 21 expect to see a reduction in physical properties? 22 A. Yes, once the degradation proceeds to some 23 level, you would see a change in the physical properties 24 of the material.</p>	<p>1 designed to protect Prolene from attack." 2 Do you see that? 3 A. I do. 4 Q. And, Doctor, if that's true, how do you account 5 for the fact that Prolene sutures have been used since 6 the 1960s? 7 A. Well, they can be used and they can have some 8 degradation, but as we said earlier, the suture, it just 9 has to hold a wound closed and the wound heals around it 10 and it's basically done its job. It can have cracking 11 in it, and it can stiffen, and that's okay. 12 That's different from a pelvic mesh where the 13 mesh has to be flexible to move with the soft tissue. 14 Q. The attack that you reference is by reactive 15 oxygen species; correct? 16 A. Yes. 17 Q. And reactive oxygen species, they possess a 18 free radical? 19 A. They generate radicals, yes. 20 Q. And -- well, but they possess a free radical, 21 don't they, sir? 22 A. Well, if you consider hydrogen peroxide to be a 23 reactive oxygen species, it's H<sub>2</sub>O<sub>2</sub>, it does not have a 24 radical in there, but if you heat it up or expose it to</p>
<p style="text-align: center;">Page 115</p> <p>1 Q. Okay. And you'd never expect to see an 2 increase in physical properties with degradation? 3 A. Certain properties could be improved with 4 oxidation. 5 Q. What properties -- what physical properties 6 would be improved with oxidative degradation occurring 7 in the body? 8 A. It might improve solvent resistance. It might 9 improve something else. I just hate to say never. 10 Q. I understand that, but my question to you is, 11 Doctor: Would you ever expect to see an increase in 12 physical properties if a material is degraded 13 oxidatively in vivo? 14 A. For example, with Prolene, you see an 15 improvement in modulus. If you're looking for 16 stiffness, you can stiffen the material by an oxidative 17 degradation process. 18 Q. Doctor, let's look on page 13 of your report. 19 At the very bottom, it states -- well, at the bottom of 20 page 13, you discuss Santonox R and DLTDP. Do you see 21 that? 22 A. Yes, I do. 23 Q. And at the bottom of 13, you say: "Neither of 24 these antioxidants," i.e., Santonox R or DLTDP," is</p>	<p style="text-align: center;">Page 117</p> <p>1 appropriate conditions, then it can form free radicals. 2 Q. Well, a reactive oxygen species has a nonbonded 3 electron that wants to bond to something, doesn't it? 4 A. Well, you could consider it to be a reactive 5 oxygen species, even that H<sub>2</sub>O<sub>2</sub>, in its molecular form. 6 It's still a reactive oxygen-containing species. 7 Q. Right, but a free radical is not bonded, is it, 8 sir? 9 A. A free radical has an unpaired electron, that's 10 right. 11 Q. Okay. And an unpaired electron means that it's 12 not bonded; correct? 13 A. That's right. 14 Q. Okay. And a free radical is a free radical is 15 a free radical, regardless of the origin? 16 A. Well, there are all sorts of different free 17 radicals with all different sorts of reactivity or 18 stability, depending on how you want to look at it. 19 They're not all the same. 20 Q. Is there any difference between a free radical 21 formed in the body and one that's formed in the 22 extrusion or heating process? 23 A. There may well be different things that are 24 formed.</p>

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<p>1 Q. Santonox R and DLTDP are free radical 2 scavengers, aren't they?</p> <p>3 A. Actually, Santonox preferentially reacts with 4 the oxygen-containing species, but the -- what's it 5 called? --</p> <p>6 Q. DLTDP?</p> <p>7 A. -- that guy is a free radical scavenger.</p> <p>8 Q. Okay. And it's your testimony that Santonox R 9 is not a free radical scavenger?</p> <p>10 A. Well, it primarily works by reacting with the 11 oxygen itself.</p> <p>12 Q. But is it a free radical scavenger, sir?</p> <p>13 A. At some level, yes.</p> <p>14 Q. Thank you. And, in fact, that's their job is 15 to remove free radicals that want to bond?</p> <p>16 A. That's certainly part of their job, yes.</p> <p>17 Q. And, at a minimum, you'll agree that Santonox R 18 and DLTDP are designed to retard the formation of free 19 radicals?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And, Doctor, do you have a solution for 22 what types of antioxidants should be used to prevent 23 oxidation in the pelvic floor region?</p> <p>24 A. I simply don't think that there's adequate</p>	<p>1 oxidative degradation inside the body for the lifetime 2 of an implant.</p> <p>3 Q. Okay. And how much antioxidants should be put 4 in there to prevent lifetime degradation of an implant?</p> <p>5 A. There would have to be more.</p> <p>6 Q. Can you tell us that concentration level?</p> <p>7 A. I cannot tell you the exact concentration 8 level. One would have to do experiments.</p> <p>9 Q. And you've not done any of those experiments; 10 correct?</p> <p>11 A. No, and I don't think Ethicon has either.</p> <p>12 Q. And if you'd look at page 14 of your report, 13 you cite Liebert?</p> <p>14 A. Yes.</p> <p>15 Q. I presume you'd consider Liebert authoritative?</p> <p>16 A. Yes.</p> <p>17 Q. And you'll agree that there was no loss of 18 molecular weight with the fiber that Liebert studied 19 that had antioxidants in it?</p> <p>20 A. Not under the conditions that they carried out 21 the study.</p> <p>22 Q. Thank you. And, Doctor, you will also agree 23 that the fiber with antioxidants showed no changes in 24 molecular weight?</p>
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<p>1 antioxidants out there to render polypropylene 2 permanently stable to oxidative effects inside the body.</p> <p>3 Q. And, Doctor, do you have an alternative to 4 DLTDP or Santonox R to prevent oxidizing degradation?</p> <p>5 A. I don't think there's an antioxidant package 6 out that that will do it, as I just said. You can try 7 to add more, but the antioxidants themselves have 8 toxicity issues.</p> <p>9 Q. And, Doctor, you have no opinion on the 10 concentration levels of Santonox R or DLTDP, do you?</p> <p>11 A. Well, in general, if you're trying to prevent 12 the oxidative degradation, more is better, but the human 13 body, the fact that it's to be used inside the body and 14 the fact that the Santonox and the DLTDP come with MSDS 15 sheets that have cautions regarding their use in the 16 body, might cause one not to put as much as possible in 17 there.</p> <p>18 Q. Do you have an opinion, sir, on whether or not 19 Ethicon's Prolene material has too much or too little 20 Santonox R and DLTDP as far as concentration levels are 21 concerned?</p> <p>22 A. Too much or too little for what?</p> <p>23 Q. To prevent oxidation.</p> <p>24 A. There's not enough in there to prevent</p>	<p>1 A. They did observe changes in molecular weight.</p> <p>2 Q. Of the fiber with antioxidants?</p> <p>3 A. But that was for a fiber without antioxidants 4 in there.</p> <p>5 Q. But for the fiber with antioxidants, there was 6 no change in molecular weight; correct?</p> <p>7 A. They did not detect any, that's correct.</p> <p>8 Q. Right. And, in fact, sir, the fiber with 9 antioxidants showed no lowering of the glass transition 10 temperature, did it?</p> <p>11 A. I would have to go back and look at that.</p> <p>12 Q. Liebert didn't do any cleaning of the fibers, 13 did he?</p> <p>14 A. I don't recall that Liebert did cleaning. Again, I'd have to look at the paper.</p> <p>15 Q. Sir, do you know if Liebert even used Prolene?</p> <p>16 A. As I recall, Liebert was using a Pro-fax polypropylene, and I know Pro-fax pretty well, because 17 that was a Hercules polypropylene.</p> <p>18 Q. But, Doctor, you can't testify under oath that Liebert used a Prolene product, can you?</p> <p>19 A. No.</p> <p>20 Q. Turning to page 15, Jongebloed, we've talked about that; right?</p>

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<p>1 A. Yes.</p> <p>2 Q. Doctor, that's -- it was a suture implanted in</p> <p>3 the eye for six and a half years?</p> <p>4 A. Yes, the first study was.</p> <p>5 Q. And you'll agree that UV light causes</p> <p>6 degradation?</p> <p>7 A. UV light can cause degradation, yes.</p> <p>8 Q. Doctor, do you believe that there were hydrogen</p> <p>9 peroxides in the eye that caused degradation of the</p> <p>10 sutures?</p> <p>11 A. There certainly could have been, yes.</p> <p>12 Q. And you'll agree that the eye is full of</p> <p>13 proteins, wouldn't you?</p> <p>14 A. There's proteins in the eye.</p> <p>15 Q. In fact, that's what builds up on contacts?</p> <p>16 A. Yes.</p> <p>17 Q. That's what you've seen in your work?</p> <p>18 A. Yes.</p> <p>19 Q. The authors didn't do any SEM or FTIR analyses,</p> <p>20 did they?</p> <p>21 A. They did SEM analysis.</p> <p>22 Q. But they didn't do any FTIR, did they?</p> <p>23 A. Again, we could go back and look at the paper.</p> <p>24 I don't recall any.</p>	<p>1 A. Can we look in there?</p> <p>2 Q. Absolutely.</p> <p>3 A. They did carry out a cleaning study.</p> <p>4 Q. My question is, sir: The FTIR analysis in Mary</p> <p>5 did not show a peak at 1740 reciprocal centimeters for</p> <p>6 the DLTDP wavelength; correct?</p> <p>7 A. They measured the absorbance at 1740.</p> <p>8 Q. Yes, sir, but did they recognize that</p> <p>9 wavelength for DLTDP, is my question?</p> <p>10 A. They did not, but they had cleaned the sample,</p> <p>11 and that would remove surface antioxidants. Plus, the</p> <p>12 sutures had been in the body for two years, which would</p> <p>13 also deplete antioxidants present at the surface.</p> <p>14 Q. The authors in Mary didn't compare the</p> <p>15 elongation of Prolene to PVDF, did they?</p> <p>16 A. Compare the elongation of the Prolene and the</p> <p>17 PVDF?</p> <p>18 Q. That's correct.</p> <p>19 A. PVDF? I don't see the comparison.</p> <p>20 Q. Doctor, on page 20 of your expert report,</p> <p>21 there's an SEM photograph?</p> <p>22 A. Yes.</p> <p>23 Q. That's not a -- that's not a Prolene product,</p> <p>24 is it? Top of page 20.</p>
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<p>1 Q. Okay. Let's look at -- continuing on page 15,</p> <p>2 at the bottom, you cite the Mary article?</p> <p>3 A. Yes.</p> <p>4 Q. And we've talked about Mary already; is that</p> <p>5 right?</p> <p>6 A. Yes.</p> <p>7 Q. And, Doctor, you'll agree that the authors in</p> <p>8 Mary did not recognize 1740 as a wavelength for DLTDP?</p> <p>9 A. I don't know that, but I have no evidence that</p> <p>10 they explicitly pointed that out.</p> <p>11 Q. Well, did the study -- did the Mary study, sir,</p> <p>12 recognize a 1740 wavelength for DLTDP?</p> <p>13 A. I did not see that called out in there.</p> <p>14 Q. And, in fact, sir, if -- how would you know</p> <p>15 that -- first of all, Prolene has DLTDP in it, doesn't</p> <p>16 it?</p> <p>17 A. Yes, it does.</p> <p>18 Q. And if the Mary article did not have a</p> <p>19 wavelength at 1740 reciprocal centimeters for DLTDP, how</p> <p>20 in the world do you know it's Prolene that they were</p> <p>21 looking at?</p> <p>22 A. I'm not sure I follow you.</p> <p>23 Q. Okay. Well, the FTIR analysis in Mary did not</p> <p>24 show a peak at 1740 reciprocal centimeters?</p>	<p>1 A. Let me see. That's from Lefranc, and that's</p> <p>2 actually from Clave's study, so Clave obtained the</p> <p>3 polypropylene vaginal meshes from a variety of</p> <p>4 manufacturers, and so it could be, but it may not be.</p> <p>5 Q. You can't testify to a reasonable degree of</p> <p>6 scientific certainty that the photograph on the top of</p> <p>7 page 20 is a Prolene product, can you?</p> <p>8 A. No, I can't.</p> <p>9 Q. And, Doctor, on page 21 of your expert report,</p> <p>10 you discuss plasticization?</p> <p>11 A. Yes.</p> <p>12 Q. Do you believe that the Prolene implants on</p> <p>13 these 28 plaintiffs plasticized in vivo?</p> <p>14 A. I believe there is the possibility that some</p> <p>15 plasticization could take place during the process</p> <p>16 inside the body, along with oxidative degradation.</p> <p>17 Q. And, Doctor, is it your opinion to a reasonable</p> <p>18 degree of scientific certainty that the implants in</p> <p>19 these 28 plaintiffs plasticized?</p> <p>20 A. There certainly could have been some</p> <p>21 plasticization of those implants.</p> <p>22 Q. Is that a yes?</p> <p>23 A. Yes, I believe it could happen.</p> <p>24 Q. What effect does plasticization have on the</p>

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<p style="text-align: center;">Page 126</p> <p>1 physical properties of Prolene?</p> <p>2 A. That will actually soften the material.</p> <p>3 Q. And it softens it by a small molecule being</p> <p>4 absorbed into it?</p> <p>5 A. That's correct.</p> <p>6 Q. You've never tested plasticization, have you,</p> <p>7 sir?</p> <p>8 A. Well, I've actually encountered plasticization</p> <p>9 in the course of my career, but I haven't tested it</p> <p>10 with --</p> <p>11 Q. Prolene?</p> <p>12 A. -- directly with Prolene.</p> <p>13 Q. Thank you. And, Doctor, page 25, in the full</p> <p>14 paragraph in the middle, where you discuss the waxy</p> <p>15 scrapings, do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. Now, Bracco, which is one of your references,</p> <p>18 that shows that cyclohexane extracts nonpolar fatty</p> <p>19 acids, correct?</p> <p>20 A. Correct.</p> <p>21 Q. And nonpolar fatty material would be a</p> <p>22 contaminant of Prolene, would it not?</p> <p>23 A. It could be a contaminant in there, yes.</p> <p>24 Q. And the presence of nonpolar fatty material</p>	<p style="text-align: center;">Page 128</p> <p>1 oxidizers. Did I read that correctly?</p> <p>2 A. No, the MSDS sheet states that polypropylene is</p> <p>3 incompatible with strong oxidizers.</p> <p>4 Q. Sorry. You said "incompatible"?</p> <p>5 A. Yeah, polypropylene is incompatible with strong</p> <p>6 oxidizers.</p> <p>7 Q. Do you have that material safety data sheet</p> <p>8 with you, sir?</p> <p>9 A. Yes.</p> <p>10 Q. That's the Sunoco material safety data sheet;</p> <p>11 is that right?</p> <p>12 A. Yes, it's Sunoco. At least I did have it.</p> <p>13 There we go.</p> <p>14 Q. And it states that polypropylene is</p> <p>15 incompatible with strong oxidizers, on page 4? That's</p> <p>16 what you wrote in your report; right?</p> <p>17 A. Yeah, on page 4, it says: "The following</p> <p>18 materials are incompatible with this product."</p> <p>19 Q. And if you -- I'm sorry --</p> <p>20 A. It lists a variety of strong oxidizers.</p> <p>21 Q. Right. And, Doctor, if you look at page 5, it</p> <p>22 says: "No epidemiological studies or case reports</p> <p>23 suggest any serious chronic health hazards from</p> <p>24 long-term exposure to polypropylene."</p>
<p style="text-align: center;">Page 127</p> <p>1 would lower a melting point, would it not, sir?</p> <p>2 A. It would not lower the melting point. It would</p> <p>3 not get into the crystalline region of the material. It</p> <p>4 would get into the amorphous material and lower its</p> <p>5 class transition temperature.</p> <p>6 Q. Doctor, on page 26 of your expert report, you</p> <p>7 discuss a material safety data sheet. Do you see that?</p> <p>8 A. Okay. We're on page 26 now, at the top. Okay.</p> <p>9 Q. Yes, sir.</p> <p>10 A. Yes.</p> <p>11 Q. And I may have asked you this earlier and I've</p> <p>12 forgotten. Have you ever developed or designed a</p> <p>13 polypropylene product?</p> <p>14 A. I have synthesized polypropylene.</p> <p>15 Q. And what did the -- when you say "synthesized,"</p> <p>16 what did you do?</p> <p>17 A. Made it from small molecule precursors by the</p> <p>18 polymerization process.</p> <p>19 Q. For a medical product?</p> <p>20 A. Not for a medical product.</p> <p>21 Q. For what type of product?</p> <p>22 A. Research. R &amp; D.</p> <p>23 Q. And, Doctor, you state here at the top of page</p> <p>24 26 that the MSDS should not be used with strong</p>	<p style="text-align: center;">Page 129</p> <p>1 Did I read that correctly?</p> <p>2 A. No. Actually, it says: "No epidemiological</p> <p>3 studies or case reports suggest any serious chronic</p> <p>4 health hazards from long-term exposure to polypropylene</p> <p>5 decomposition products below the irritation level."</p> <p>6 Q. Why didn't you quote that in your report,</p> <p>7 Doctor?</p> <p>8 A. Well, I very well could have quoted that.</p> <p>9 Q. Why did you not quote that, Doctor?</p> <p>10 A. My report is basically about oxidative</p> <p>11 degradation of polypropylene.</p> <p>12 (Mays Exhibit No. 5 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. HUTCHINSON:</p> <p>15 Q. I'll hand you what we'll mark as Exhibit 5 to</p> <p>16 your deposition. This is a copy of peer-reviewed</p> <p>17 literature that you're one of five authors on; is that</p> <p>18 right?</p> <p>19 A. Yes.</p> <p>20 Q. And, Doctor, before we start this, let me ask</p> <p>21 you this: If you were going to submit an article to</p> <p>22 your peers at the American Chemical Society about the</p> <p>23 degradation of polyurethane, you'd want to study a</p> <p>24 polyurethane product; right?</p>

33 (Pages 126 to 129)

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<p>1 A. Yes.</p> <p>2 Q. Okay. None of these products that are</p> <p>3 referenced in the Imel article are Prolene, are they,</p> <p>4 sir?</p> <p>5 A. These particular polypropylenes are isotactic</p> <p>6 polypropylene of the Marlex variety. Prolene is an</p> <p>7 isotactic polypropylene.</p> <p>8 Q. But I'm not talking about the chemistry,</p> <p>9 Doctor. I'm asking you whether or not your study used</p> <p>10 Prolene products. Yes or no?</p> <p>11 A. No, we used polypropylene from Marlex. Marlex</p> <p>12 polypropylene.</p> <p>13 Q. In fact, Doctor, your study did not even</p> <p>14 study -- strike that.</p> <p>15 Your study didn't even discuss Prolene</p> <p>16 products, did it?</p> <p>17 A. We do mention Ethicon products at several</p> <p>18 points in here. If you look on page 1, the last</p> <p>19 paragraph, we're talking about Costello, References 9</p> <p>20 and 10. They studied explanted polypropylene hernia</p> <p>21 meshes from CR Bard and Ethicon.</p> <p>22 Q. I'm not talking about the literature. I'm</p> <p>23 talking about Prolene products.</p> <p>24 A. As I've already said, the polypropylene samples</p>	<p>1 Also, when we examined the materials under the</p> <p>2 SEM, we used EDS. EDS is spectroscopy that detects</p> <p>3 whether certain elements are there. So by looking for</p> <p>4 the presence of oxygen, we could see where oxidation had</p> <p>5 taken place on the fiber. If we saw oxygen and</p> <p>6 nitrogen, the nitrogen would tell us that we could have</p> <p>7 proteins there.</p> <p>8 Q. Doctor, on page 1, the first sentence under</p> <p>9 "introduction" says: "Polypropylene has been used for</p> <p>10 hernia repair since 1958."</p> <p>11 Do you see that?</p> <p>12 A. Yes, sir.</p> <p>13 Q. How do you reconcile the fact that Prolene mesh</p> <p>14 has been used since 1958 in hernia repair with your</p> <p>15 opinions regarding oxidation?</p> <p>16 A. Well, again, as I've said before, I don't</p> <p>17 condemn polypropylene universally as a biomaterial, and</p> <p>18 that includes Prolene polypropylene. It has uses.</p> <p>19 This oxidative degradation is occurring for</p> <p>20 polypropylenes inside the human body, but you can have</p> <p>21 some oxidative degradation in a suture or some oxidative</p> <p>22 degradation in a hernia mesh and not have a problem. I</p> <p>23 think a pelvic mesh, because of how the mesh is supposed</p> <p>24 to function inside the body, it's a different material.</p>
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<p>1 that we characterized in this work were explanted Marlex</p> <p>2 samples.</p> <p>3 Q. Doctor, page 1, under the abstract, it says:</p> <p>4 "SEM revealed the formation of transverse cracking on</p> <p>5 the fibers which generally, but with some exceptions,</p> <p>6 increased with implantation time."</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And, Doctor, it's well-known that proteins</p> <p>10 adhere to biomaterials within seconds; is that right?</p> <p>11 A. Yes.</p> <p>12 Q. And, Doctor, what did you do to rule out an</p> <p>13 increased layer of proteins building up over</p> <p>14 implantation time?</p> <p>15 A. Yeah. We did a couple of things. We cleaned</p> <p>16 the materials before we performed the FTIR by using a</p> <p>17 bleach solution. That's the ASTM protocol for cleaning</p> <p>18 up the material.</p> <p>19 Also, that's what was done by Dr. Gajanan, I</p> <p>20 guess, the gentleman who provided the explanted Prolene</p> <p>21 samples to Ethicon scientists that they then studied</p> <p>22 with FTIR.</p> <p>23 So we cleaned the materials up to remove the</p> <p>24 tissue, the proteins that were on there.</p>	<p>1 Q. And, Doctor, on page 132 you cite Lefranc;</p> <p>2 correct?</p> <p>3 A. I'm sorry. On page --</p> <p>4 Q. 132.</p> <p>5 A. Yes.</p> <p>6 Yes, I see that now.</p> <p>7 Q. Lefranc didn't do any testing, did he?</p> <p>8 A. He did not.</p> <p>9 Q. He just recited the literature that was out</p> <p>10 there?</p> <p>11 A. It's a review article, basically.</p> <p>12 Q. And, Doctor, page 134 states that the samples</p> <p>13 were preserved in glass jars of formalin?</p> <p>14 A. Yes.</p> <p>15 Q. And this is where you're talking about the 11</p> <p>16 explants of Boston Scientific patients?</p> <p>17 A. Yes.</p> <p>18 Q. And do you know how long these explants were</p> <p>19 preserved in formalin?</p> <p>20 A. I can't recall as I sit here. I think I did</p> <p>21 see that information at some point.</p> <p>22 Q. And, Doctor, you'll agree that the explants had</p> <p>23 protein on them before they were put in the glass jars</p> <p>24 of formalin?</p>

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<p>1 A. Yes.</p> <p>2 Q. And, Doctor, did you consider the chemical 3 reaction between formalin and protein in its formation 4 of a new polymer?</p> <p>5 A. No, we basically removed the tissue that was on 6 there with the bleach treatment.</p> <p>7 Q. Doctor, what effect does formalin have on 8 tissue?</p> <p>9 A. The detailed interaction between formalin and 10 tissue I'm not familiar with.</p> <p>11 Q. And, Doctor, you'll agree that formaldehyde, or 12 formalin -- strike that.</p> <p>13 You'll agree that formalin and proteins 14 crosslink to form a new polymer?</p> <p>15 A. I don't know that.</p> <p>16 Q. And, Doctor, do you know whether or not 17 formalin and protein create a polymer that acts as a 18 hard casing around the fiber?</p> <p>19 A. We saw absolutely no evidence to support that. 20 In fact, we have strong evidence to shoot down that 21 theory. We simply did not see that.</p> <p>22 Q. And, Doctor, you'll agree that formaldehyde and 23 proteins chemically bond to form a new polymer?</p> <p>24 A. I don't see any evidence of that happening in</p>	<p>1 Q. And you would agree that formaldehyde is a 2 fixation agent, wouldn't you?</p> <p>3 A. Yes, I would agree with that.</p> <p>4 Q. All right. And formaldehyde, if it fixes 5 something on a slide, that means that it makes that 6 biological material hard; correct?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Doctor, if you look at page 134, you 9 discuss the cleaning of these explanted specimens. Do 10 you see that? Middle of page 134.</p> <p>11 A. Yes, I see that now.</p> <p>12 Q. And you followed ISO 12891?</p> <p>13 A. Yes.</p> <p>14 Q. And that's not a protocol for cleaning 15 polypropylene, is it?</p> <p>16 A. It's a protocol for cleaning polyethylene. I 17 looked for an ASTM or ISO protocol for cleaning 18 polypropylene, and I couldn't find one. And 19 polypropylene is chemically very similar to 20 polyethylene.</p> <p>21 Also, I'll add, this is the same method that 22 Professor Gajanan, or however his name is pronounced, 23 used when he had Prolene explanted samples. He cleaned 24 them with the same bleach treatment before he provided</p>
<p style="text-align: center;">Page 135</p> <p>1 this case, so I don't agree.</p> <p>2 Q. I'm asking you as a materials scientist. Is it 3 your opinion that formaldehyde and proteins do not 4 chemically bond to form a new polymer?</p> <p>5 A. I don't know of a situation where that occurs. 6 You'd have to show me the literature.</p> <p>7 Q. Doctor, can you draw out the chemical structure 8 of a polymer?</p> <p>9 A. Yes.</p> <p>10 Q. Can you draw out the chemical structure of a 11 formaldehyde and protein polymer?</p> <p>12 A. I'm not really sure how that interaction would 13 occur. It would depend on what kind of protein you're 14 talking about and what kind of functional groups were 15 present on it.</p> <p>16 Q. Doctor, if you look on page 134 -- well, before 17 we move there, Doctor, you will agree that formaldehyde 18 fixes tissue; correct?</p> <p>19 A. Yes, I've heard that said, yes.</p> <p>20 Q. In fact, you'll agree that formaldehyde makes 21 tissue hard enough so that it could be sliced in the 22 microtoming process when creating histology slides; 23 you'll agree with that?</p> <p>24 A. Yes, I'll agree with that.</p>	<p style="text-align: center;">Page 137</p> <p>1 them to Dr. Buckley of Ethicon.</p> <p>2 Q. Doctor, are you aware of any ISO protocol 3 specifically for cleaning polypropylene or Prolene?</p> <p>4 A. I was not able to find one for polypropylene or 5 Prolene.</p> <p>6 Q. And, Doctor, are you aware of any protocol 7 whatsoever to remove a protein-formaldehyde polymer?</p> <p>8 A. I haven't explicitly looked for it, but when we 9 did our SEM with EDS, we found clean regions with only 10 carbon and oxygen, no protein present on the material.</p> <p>11 Q. Doctor, you only did one cycle of cleaning; 12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. And you only did 24 hours?</p> <p>15 A. Yes, that's correct.</p> <p>16 Q. Why did you choose 24 hours?</p> <p>17 A. Because it was standard protocol. It's what we 18 saw in the ISO standard. It's what we saw that others 19 had used in the literature when they cleaned up 20 polypropylene explants.</p> <p>21 Q. And you only used sodium hypochlorite and not 22 an enzyme; correct?</p> <p>23 A. That's correct.</p> <p>24 Q. Why didn't you use an enzyme?</p>

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<p>1       A. Because this seemed to be the best protocol to 2       use.</p> <p>3       Q. Doctor, did this protocol clean 100 percent of 4       the biological residue off the fibers?</p> <p>5       A. As I keep saying, our SEM with EDS can tell us 6       where clean regions are and where they're not. There 7       were regions which were not completely clean, that's 8       correct.</p> <p>9       Q. And, Doctor, you followed extensively by 10      rinsing?</p> <p>11      A. Yes.</p> <p>12      Q. With water?</p> <p>13      A. Yes.</p> <p>14      Q. What was the temperature of the water?</p> <p>15      A. Room temperature.</p> <p>16      Q. Why wasn't that included in your report?</p> <p>17      A. Didn't seem relevant. You can't include 18      everything in the report.</p> <p>19      Q. Did you do any sonication?</p> <p>20      A. We did not sonicate.</p> <p>21      Q. Did you use distilled water?</p> <p>22      A. Yes.</p> <p>23      Q. Was the water changed out?</p> <p>24      A. Yes.</p>	<p>1       look at the polypropylene with no oxidation, just as it 2       comes out of the package.</p> <p>3       Q. Doctor, are you aware that you can go to the 4       library and get the spectra of polypropylene without 5       having to do a spectra?</p> <p>6       A. Of course we know that.</p> <p>7       Q. And, Doctor, were FTIRs done before the 8       cleaning process to confirm the presence of proteins?</p> <p>9       A. We did not.</p> <p>10      Q. And, Doctor, why not?</p> <p>11      A. Well, it was clear just visually that protein 12      was on there.</p> <p>13      Q. And, Doctor, were FTIRs done after the cleaning 14      process to confirm the complete removal of protein?</p> <p>15      A. Yes, FTIRs were run.</p> <p>16      Q. And, Doctor, were FTIRs done after the cleaning 17      process to confirm that you were analyzing completely 18      clean polypropylene fibers?</p> <p>19      A. FTIR was done on the clean fibers. We used the 20      SEM with EDS to look at the materials, and we could see 21      that we had done a very good job of cleaning, although 22      we could in some instances find regions where there was 23      still some tissue there.</p> <p>24      Q. Doctor, is this the only cleaning process that</p>
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<p>1       Q. Why wasn't that included in the report?</p> <p>2       A. Again, when you're publishing a peer-reviewed 3       paper, you can't include every single detail.</p> <p>4       Q. Was the water tested at all, sir?</p> <p>5       A. We used deionized water.</p> <p>6       Q. Okay. But my question is: Was the water 7       tested?</p> <p>8       A. We have a conductivity meter connected to it, 9       and it has to pass a certain standard for deionization.</p> <p>10      Q. Was the water tested, sir, to determine if any 11      proteins were removed?</p> <p>12      A. No, we did not.</p> <p>13      Q. Was the water tested, sir, to determine if any 14      polypropylene was removed?</p> <p>15      A. No.</p> <p>16      Q. Doctor, what FTIRs -- I'm sorry. Strike that. 17      Were FTIRs done on pristine polypropylene?</p> <p>18      A. Yes.</p> <p>19      Q. And that was done to determine what the spectra 20      looks like?</p> <p>21      A. Yes.</p> <p>22      Q. Why did y'all do FTIRs on pristine 23      polypropylene?</p> <p>24      A. Because we wanted the baseline. We wanted to</p>	<p>1       you used to remove the protein-formaldehyde polymer?</p> <p>2       A. Yes, this is the process we used.</p> <p>3       Q. And, Doctor, sitting here today, is this the 4       first time you've ever heard of the formation of a 5       protein-formaldehyde polymer when those two agents 6       interact?</p> <p>7       A. I'm not familiar with the exact structure of 8       what's being formed there. I know you use formaldehyde 9       and formalin to fix tissue.</p> <p>10      Q. My question, though, is: Sitting here today, 11      is this the first time that you've ever heard of the 12      formation of a protein and formaldehyde polymer?</p> <p>13      A. I'm not familiar with what you're referring to 14      there.</p> <p>15      Q. All right. But my question is: Today, 16      March 2, 2016, is this the first time that you've ever 17      heard of the formation of a protein-formaldehyde 18      polymer?</p> <p>19      A. Yes.</p> <p>20      Q. And, Doctor, you can't testify to a reasonable 21      degree of scientific certainty that all the protein was 22      removed from these fibers, can you?</p> <p>23      A. Well, it's all summarized in our report here. 24      We did see some regions that contained biological tissue</p>

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<p>1 on the material even after the cleaning process, but we      2 observed a lot of areas where there was damaged surface      3 of the fiber and we only saw carbon and oxygen present.      4 Q. And, Doctor, for the biological tissue that was      5 present, that was on the mesh explants; right?      6 A. Yes.      7 Q. And you put those mesh explants into a vacuum,      8 didn't you?      9 A. Yes.      10 Q. And, in fact, you put them into a vacuum oven,      11 didn't you?      12 A. Yes.      13 Q. And how long were they put into the vacuum      14 oven?      15 A. They were in that vacuum oven overnight.      16 Q. At what temperature were they in the vacuum      17 oven?      18 A. At room temperature, as it indicates on page      19 134.      20 Q. But the purpose of putting them in a vacuum      21 oven was to dry them; correct?      22 A. Correct.      23 Q. And that would have dried any type of      24 protein-formaldehyde polymer; correct?</p>	<p>1 A. That's correct.      2 Q. And, in fact, a formaldehyde-protein polymer      3 would be a compound, wouldn't it?      4 A. It would.      5 Q. And it wouldn't be detected by EDS, would it?      6 A. Well, it would have nitrogen in there because      7 that's always in proteins, and it would have carbon in      8 there, and it would have oxygen in there.      9 Q. But, in fact, sir, nitrogen is the hardest      10 thing to find on an EDS, isn't it?      11 A. You can find nitrogen in there.      12 Q. Is it hard to find on EDS, sir?      13 A. No. We found it readily. In the SEM with EDS,      14 we see nitrogen readily.      15 Q. EDS cannot tell you or determine the origin of      16 the element, can it?      17 A. Only that the element's there.      18 Q. Can't tell you where oxygen came from, can it?      19 A. Only that it's there.      20 Q. And if oxygen is present, sir, that means you      21 can be looking at biological material?      22 A. No. If you've got only carbon and oxygen      23 present, that's strongly suggestive of an oxidative      24 process. Also, we see chain cleavage of these</p>
<p style="text-align: center;">Page 143</p> <p>1 A. Yes, it would have dried whatever was there,      2 yes.      3 Q. In fact, it would have dried that      4 protein-formaldehyde fiber -- strike that.      5 It would have dried that formaldehyde-protein      6 polymer on the fiber itself, wouldn't it?      7 A. If it were there, it would have dried it, yes.      8 Q. Doctor, on page 134 of your report -- I'm      9 sorry -- of your article, in the right-hand side, it      10 says: "Previous published work has shown that      11 preservation of explanted samples in formalin did not      12 alter the structure and chemistry."      13 Do you see that?      14 A. Yes, I see that.      15 Q. You cite Bracco; correct?      16 A. Yes.      17 Q. In fact, Bracco did not analyze Prolene in his      18 article, did he?      19 A. No.      20 Q. Doctor, on page 135, you discuss EDS; is that      21 right?      22 A. Yes.      23 Q. And EDS, that can only determine elements      24 present, not compounds; right?</p>	<p style="text-align: center;">Page 145</p> <p>1 materials. If you're seeing carbon and oxygen and      2 nitrogen, then you've got biological material.      3 Q. Biological material such as protein contains      4 nitrogen -- I'm sorry -- oxygen, doesn't it?      5 A. Yes, but you would see nitrogen too.      6 Q. Doctor, on page 138, you state, at the bottom:      7 "FTIR shows peaks."      8 Do you see that?      9 A. Let's see.      10 Q. Bottom of page 138.      11 A. On the left side?      12 Q. Yes, sir.      13 A. Okay. I see -- under the discussion?      14 Q. Yep.      15 A. Okay.      16 Q. My question is: How can you distinguish a      17 carbonyl band at 1740 as a result of oxidation and      18 carbonyl bands of ketones, aldehydes, and carboxylic      19 acids in the same range?      20 A. All those peaks show up in that same general      21 regime.      22 Q. And how can you distinguish between them, sir?      23 A. It's relatively difficult to do.      24 Q. Can you distinguish them, sir?</p>

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<p>1        A. I wouldn't say it's impossible, but it's 2        difficult.</p> <p>3        Q. Can you, as an expert in this litigation, 4        distinguish between those peaks, sir?</p> <p>5        A. Between the ketone, aldehyde, and carboxylic 6        acid?</p> <p>7        Q. And oxidation. Can you distinguish between all 8        those peaks on a FTIR spectra?</p> <p>9        A. Oxidative degradation gives a mixture of 10      products, and all of these contain the carbonyl, and so 11      you have overlapping peaks, so it's hard to resolve them 12      and really tell exactly how much you have of one versus 13      how much you have of the other.</p> <p>14      Q. My question is: Yes or no, can you distinguish 15      between all these peaks?</p> <p>16      A. Well, you're going to have to ask me a more 17      clear question that I can really understand.</p> <p>18      Q. You as an expert in this mesh litigation, can 19      you distinguish between the peaks of oxidation, ketones, 20      aldehydes, or carboxylic acids?</p> <p>21      A. Well, oxidation gives ketones, aldehydes, and 22      carboxylic acids, so, you know, these are three 23      different oxidative degradation products.</p> <p>24      Q. I'm sorry, but are you testifying that</p>	<p>1        that's page 141, at Figure 8, what we're seeing in those 2        materials is the fiber cracking, which is a strong sign 3        of oxidation in these materials, and we see that 4        cracking is occurring, you know, after a year in most of 5        the samples. Not all of them, but most of the samples 6        show cracking after a year. So I would say sometime 7        around a year is a good ballpark.</p> <p>8        Q. But you can't tell us a specific time; correct?</p> <p>9        A. I can tell you about a year. And it's going to 10      vary from individual to individual, as we talked about 11      earlier. You put the same mesh in two different women 12      and they might respond differently to it. Bodies are 13      different.</p> <p>14      Q. Doctor, did you review the Ethicon's seven-year 15      dog study?</p> <p>16      A. Yes, I saw that document. (Mays No. 6 was marked for identification.)</p> <p>17      BY MR. HUTCHINSON:</p> <p>18      Q. Hand you what we'll mark as Exhibit 6. And, 19      Doctor, this is a document you relied on; is that right?</p> <p>20      A. I have seen this document.</p> <p>21      Q. And you relied on it; correct?</p> <p>22      A. Yes.</p> <p>23      Q. Did you notice anything -- what did you notice</p>
<p>1        oxidation causes ketones?</p> <p>2        A. Yes.</p> <p>3        Q. Are you testifying that oxidation causes 4        aldehydes?</p> <p>5        A. Yes.</p> <p>6        Q. And can you tell, sir, as an expert in this 7        mesh litigation, can you distinguish between the peaks 8        of aldehydes, ketones, or carboxylic acids?</p> <p>9        A. In the case where they're all being formed and 10      there's a mixture of them, they're overlapping and 11      they're so close together, we didn't even try to 12      deconvolute the peaks and separate out how much of one 13      we have versus the other.</p> <p>14      Q. Doctor, on page 140: "Antioxidants are 15      preferentially consumed by the oxidizing species."</p> <p>16      Do you see that?</p> <p>17      A. Yes.</p> <p>18      Q. And you can't tell us the rate that is 19      consumed; correct?</p> <p>20      A. Not the exact, right, no.</p> <p>21      Q. And, Doctor, can you tell us the point in time, 22      a specific point in time when the oxidizing agents -- 23      I'm sorry -- the antioxidants are consumed?</p> <p>24      A. Well, if you go over and look on the next page,</p>	<p>1        about the change in mechanical or physical properties of 2        the sutures after they'd been implanted for seven years?</p> <p>3        A. Again, you'd have to take me back to that. I've seen so many of these documents.</p> <p>5        Q. Well, Doctor, before we go from that, without 6        looking at -- without looking at the specific data 7        points, what do you recall about the physical properties 8        of the sutures analyzed in the seven-year dog study?</p> <p>9        A. I don't recall the specifics of the mechanical 10      properties. I just remember that there were indications 11      of oxidation.</p> <p>12      Q. Did you look, sir, when you reviewed the 13      Burkley dog study, or the seven-year dog study, did you 14      look to see what the results of the physical property 15      testing were?</p> <p>16      A. I looked at it, but I can't remember at this point as I sit here.</p> <p>18      Q. Doctor, let's look at page 221. It's 19      ETH.MESH.221. Are you there with me?</p> <p>20      A. I am there.</p> <p>21      Q. And we have two computations of molecular 22      weight, weighted average molecular weight, number 23      average molecular weight?</p> <p>24      A. I think we're looking at different pages.</p>

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<p>1       MR. MONSOUR: I think we've got different      2       pages. My page looks like -- 221 looks like this.      3       Oh, there's a second 221 in the back. We were      4       at 336221. You're at 888221. Okay. Gotcha.      5       MR. HUTCHINSON: Always put the good stuff in      6       the back.      7       MR. MONSOUR: Of course.      8       BY MR. HUTCHINSON:      9       Q. Are you there with me, Doctor?      10      A. Yes, I'm there.      11      Q. Have you seen this particular page with the dog      12       study before today?      13      A. I have seen this before, yes.      14      Q. And did you account for this in reaching your      15       opinions?      16      A. What do you mean by did I "account" for it?      17      Q. Did you consider this particular page 221 when      18       reaching your opinions?      19      A. Yes.      20      Q. And you will agree that the molecular weight      21       differences are very, very small; correct?      22      A. Could you show me which ones you're referring      23       to?      24      Q. The ones discussing current Prolene 4/0 suture</p>	<p>1       from.      2       Q. Well, have you made any efforts to find out      3       more details?      4       A. This is all I've had to date.      5       Q. Have you made any efforts to find out more      6       details, sir?      7       A. I haven't. This is what I had at the time I      8       prepared my report. If they have more data, I would      9       love to see it.      10      Q. But sitting here today, Doctor, with all the      11       data that you have so far, do you have any reason to      12       dispute that Dr. Burkley found no molecular weight      13       degradation?      14      A. Based on what I see in this document, I cannot      15       tell how these values were derived, and what I will say      16       is one has to do the GPC analysis carefully. It's      17       difficult to perform high temperature GPC. We happen to      18       be experts in it. We've had years and years of      19       experience in it.      20      And it's the Z average molecular weight which      21       is most sensitive to degradation, and then the weight      22       average molecular weight is sensitive to degradation as      23       well. The number average molecular weight is not      24       sensitive to degradation.</p>
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<p>1       compared to Dog Site 3 and Dog Site 2. Do you see that?      2       Down at the bottom.      3       A. Yes.      4       Q. And what do you notice about the change of      5       molecular weight, Doctor?      6       A. I notice that those are not changing very much.      7       Q. And that was done by GPC; correct?      8       A. Yeah, I would assume so. That's how these      9       values are normally derived.      10      Q. And, in fact, at the bottom, under conclusions,      11       it says: "Comparison of 7-year explants to current      12       Prolene indicate no molecular weight degradation."      13      Did I read that correctly?      14      A. That's what it says.      15      Q. Any reason to dispute that, Doctor?      16      A. Well, I would need to have more details about      17       what they did, because they're also carrying out      18       intrinsic viscosity measurements here, these IV      19       measurements, and it's not clear to me whether they're      20       deriving these MW values from that IV measurement.      21       That's commonly done.      22       And maybe they're getting these number average      23       molecular weights from GPC. I simply don't know. They      24       don't clearly tell me where these values are coming</p>	<p>1       So I don't know enough about where these values      2       came from and the protocol that they use to speculate,      3       and I don't want to speculate.      4       Q. I understand, Doctor, but in all fairness,      5       these values do not support your opinions, do they?      6       A. I don't know enough about these values to be      7       able to say whether they're valid or not.      8       Q. But my question is, Doctor, the values that are      9       on this sheet of paper, do these values support your      10       opinions; yes or no?      11      A. These values here show similar number average      12       molecular weights and similar weight average molecular      13       weights.      14      Q. And do these values, Doctor, support your      15       opinions; yes or no?      16      A. It's impossible for me to say. It really is.      17       I'd have to know more. GPC calibration can change over      18       time. We ran our controls at the same time we were      19       running the explanted studies. I don't know that they      20       did this here. I simply don't have enough data.      21      Q. Doctor, do you have any explanation whatsoever      22       why Dr. Burkley found no loss of molecular weight?      23      A. I don't know whether his conclusion is valid or      24       not. I don't see enough data here for me to make a</p>

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<p>1 decision.</p> <p>2 Q. Do you have any reason to believe that these 3 sutures were plasticized?</p> <p>4 A. It is possible that polypropylene does undergo 5 some plasticization inside the body.</p> <p>6 Q. And, Doctor, plasticization would improve 7 toughness, wouldn't it?</p> <p>8 A. Plasticization would soften the material.</p> <p>9 Q. But it would improve toughness? I'm asking 10 about toughness. I'm not asking about softening the 11 material. Toughness.</p> <p>12 A. Plasticization at a reasonable level would 13 probably improve the toughness of the material.</p> <p>14 Q. Okay. And, Doctor, if toughness of the 15 material improves, then we can rule out degradation, 16 can't we?</p> <p>17 A. That's not strictly true.</p> <p>18 Q. But, Doctor, as a general rule, you will agree 19 that as toughness improves, degradation can be ruled 20 out; correct?</p> <p>21 A. I would not make a general statement about 22 that. I'd have to consider the specific material.</p> <p>23 Q. Doctor, would that be consistent with the 24 principles of polymerization that you used to teach your</p>	<p>1 increased in the third year. But I have no idea how 2 many samples were here. Is this a case of a single 3 sample?</p> <p>4 Q. Doctor, my question is: Does the data shown on 5 page ETH.MESH.183 support your opinions that Prolene 6 degrades; yes or no?</p> <p>7 A. It's impossible for me to say.</p> <p>8 Q. You can't answer that question one way or the 9 other?</p> <p>10 A. I can't.</p> <p>11 Q. And, Doctor, why can you not answer that 12 question one way or the other?</p> <p>13 A. I'd have to know more details about the study.</p> <p>14 Q. And have you made any efforts to find out more 15 details about the study?</p> <p>16 A. I have not.</p> <p>17 Q. And, Doctor, you will agree that -- let's look 18 at breaking strength. Prolene changed from baseline 19 percentage, at Year 7, it decreased 5 percent; correct?</p> <p>20 A. The breaking strength of Prolene, yes.</p> <p>21 Q. Yes. And, in fact, the elongation percentage 22 of Prolene increased, from baseline, at Year 7, 23 111 percent; correct?</p> <p>24 A. That's what this says, but how many samples?</p>
<p style="text-align: center;">Page 155</p> <p>1 students with at UT?</p> <p>2 A. Plasticization has nothing to do with the 3 principles of polymerization.</p> <p>4 Q. Would that be consistent with anything you've 5 ever discussed with your students at UT about whether or 6 not plasticization can improve toughness?</p> <p>7 A. Plasticization --</p> <p>8 Q. I'm sorry. Strike that.</p> <p>9 Doctor, turn to the last page of the Burkley 10 dog study with me, please.</p> <p>11 A. All right.</p> <p>12 Q. Doctor, you will see breaking strength at the 13 top. Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. And, by the way, did you ever consider this 16 data summary when reaching your opinions, Doctor?</p> <p>17 A. I saw this, so, yeah, I considered it.</p> <p>18 Q. Okay. And do the data shown here on page 183, 19 do the data support your opinions that the sutures 20 degraded via oxidation?</p> <p>21 A. I see the breaking strength of Prolene staying 22 roughly the same. It would be nice to see some error 23 bars on this. The elongation percent of Prolene 24 actually decreased a bit in Year 2 but seemingly</p>	<p style="text-align: center;">Page 157</p> <p>1 Q. Doctor, let's look at the Young's modulus. 2 That's just another name for stiffness, isn't it?</p> <p>3 A. Modulus is related to stiffness of the 4 material.</p> <p>5 Q. And stiffness of Prolene at Year 7 decreased 6 70 percent; correct?</p> <p>7 A. That's what this says.</p> <p>8 Q. And, Doctor, do you have any reason to believe 9 that these values are wrong?</p> <p>10 A. I'm very suspicious of these values, yes.</p> <p>11 Q. Do you have any reason to believe the values 12 are wrong, though, Doctor? I'm not asking if you're 13 suspicious.</p> <p>14 A. I need more data to really draw a firm 15 conclusion.</p> <p>16 Q. You can't tell us if these values are wrong or 17 right, can you?</p> <p>18 A. I can tell you I don't believe them.</p> <p>19 Q. And why don't you believe them?</p> <p>20 A. Because they're not realistic.</p> <p>21 Q. Which one is not realistic?</p> <p>22 A. And they're not supported.</p> <p>23 Q. Which one is not realistic? Which figure? Of 24 the -5 percent, 111, or 70 --</p>

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<p>1       A. I simply --</p> <p>2       Q. -- hold on just a minute, the court reporter is</p> <p>3       going to get made at us -- which figure do you not</p> <p>4       believe is realistic, Doctor?</p> <p>5       A. I simply cannot place faith in anything in this</p> <p>6       table. I'd have to know more about it.</p> <p>7       Q. Okay. And, Doctor, if you can't place faith in</p> <p>8       any data in this particular paper, or page, 183, can you</p> <p>9       place faith in any particular page in this dog study?</p> <p>10      A. Can you show me which one?</p> <p>11      Q. No, that's my question. My question stands.</p> <p>12      A. You know, mechanical testing of material like</p> <p>13       polypropylene has to be done carefully. You need to</p> <p>14       test multiple samples. You need to follow a protocol.</p> <p>15       I don't really see enough of the protocol here to be</p> <p>16       able to evaluate it.</p> <p>17       These data have not stood the scrutiny of peer</p> <p>18       review, to my knowledge. If they're peer-reviewed and</p> <p>19       somebody looked at them, I would accept them, but you're</p> <p>20       asking me to accept a table of data where I don't even</p> <p>21       know how many times the test was run, and so I can't</p> <p>22       comment, I can't accept it.</p> <p>23       Q. Well, Doctor, if you can't rely on the page</p> <p>24       that gives the test data, you can't rely on the</p>	<p>1       and the elongation is plotted out at Time 0; is that</p> <p>2       right?</p> <p>3       A. It says it's plotting break strength --</p> <p>4       Q. Break strength and elongation at Time 0.</p> <p>5       A. -- versus elongation, but break strength has to</p> <p>6       do with the material actually breaking. So how do you</p> <p>7       measure break strength when the material continues to</p> <p>8       elongate? These sort of data are normally presented</p> <p>9       stress versus strain. That's where you get toughness.</p> <p>10      Q. I understand. And, in fact, stress and strain</p> <p>11      is another word for breaking strength and elongation,</p> <p>12      isn't it?</p> <p>13      A. No. Breaking means failure of the sample.</p> <p>14      Stress is force per unit area. Now, percent of</p> <p>15      elongation, elongation and strain, I'll agree they're</p> <p>16      very related.</p> <p>17      Q. Elongation and strain; correct?</p> <p>18      A. Yeah, they're definitely related.</p> <p>19      Q. And breaking strength and stress are related,</p> <p>20      aren't they?</p> <p>21      A. Well, a breaking strength is the ultimate</p> <p>22      tensile strength of a material.</p> <p>23      Q. Until it breaks; correct?</p> <p>24      A. Yes.</p>
<p style="text-align: center;">Page 159</p> <p>1       conclusions of the dog study, can you?</p> <p>2       A. There may be some things in here that I think</p> <p>3       are adequately documented.</p> <p>4       Q. My question is a yes or no, and I need a yes or</p> <p>5       no. If you can't rely on the page that gives the test</p> <p>6       data, you can't rely on the conclusions of the dog</p> <p>7       study, can you; yes or no?</p> <p>8       A. Yes.</p> <p>9       Q. Yes, I'm right?</p> <p>10      A. Yes, I agree with you.</p> <p>11      (Mays Exhibit No. 7 was marked for</p> <p>12      identification.)</p> <p>13      BY MR. HUTCHINSON:</p> <p>14      Q. Doctor, handing you what we'll mark as Exhibit</p> <p>15      No. 7 to your deposition. Here we have a toughness</p> <p>16      curve; right?</p> <p>17      A. Yes.</p> <p>18      Q. And we have breaking strength as the Y axis and</p> <p>19      elongation as the X axis; correct?</p> <p>20      A. Yeah, this is kind of a peculiar way to present</p> <p>21      the data.</p> <p>22      Q. And, Doctor, this shows that toughness -- well,</p> <p>23      strike that.</p> <p>24      You can see the red where the breaking strength</p>	<p style="text-align: center;">Page 161</p> <p>1       Q. And then if you --</p> <p>2       A. But how can you plot it down here where it</p> <p>3       hasn't broken?</p> <p>4       Q. Just stay with me and my questions, Doctor.</p> <p>5       Okay?</p> <p>6       A. Okay.</p> <p>7       Q. If you look at this, this plots out at Year 0</p> <p>8       the elongation and breaking strength data points from</p> <p>9       the seven-year dog study; correct? At Year 0, under</p> <p>10      red?</p> <p>11      A. It shows elongation 37 percent and that it</p> <p>12      broke at 1.68 pounds.</p> <p>13      Q. And that's the exact data that was found in the</p> <p>14      Burkley dog study; correct?</p> <p>15      A. This looks familiar, yes.</p> <p>16      Q. And, Doctor, when we look at Year 7 on</p> <p>17      Exhibit 7, that shows the elongation at 1.6 pounds and</p> <p>18      the breaking strength -- I'm sorry, strike that.</p> <p>19      At Year 7, do you see Year 7 --</p> <p>20      A. Yes.</p> <p>21      Q. -- it shows breaking strength at 1.6 pounds; is</p> <p>22      that right?</p> <p>23      A. That's what it says, yes.</p> <p>24      Q. And it shows 78 percent elongation; correct?</p>

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<p>1 A. That's what it shows.</p> <p>2 Q. And if we look at the area under the curve for</p> <p>3 Year 7, it's much greater than at Time 0; correct?</p> <p>4 A. The area under the curve is greater, yes.</p> <p>5 Q. And, in fact, it almost doubled, didn't it?</p> <p>6 A. That would be about right, yes.</p> <p>7 Q. And, Doctor, what does this tell you about</p> <p>8 toughness when you look at the physical and mechanical</p> <p>9 properties of the sutures?</p> <p>10 A. Again, I would have to know more about this</p> <p>11 test. Was it performed 10 times and this is an average?</p> <p>12 Was it a single run? I would have to know more. I</p> <p>13 can't just take this plot out of context and draw</p> <p>14 conclusions on it.</p> <p>15 Q. Doctor, a nick in a fishing line wouldn't</p> <p>16 increase toughness, would it?</p> <p>17 A. No.</p> <p>18 Q. Doctor, can you explain -- first of all, do you</p> <p>19 agree that the data from the seven-year dog study shows</p> <p>20 an increase in toughness of the sutures?</p> <p>21 A. I don't know enough to establish the validity</p> <p>22 of this data and exactly what was done.</p> <p>23 Q. You can't answer that question yes or no?</p> <p>24 A. No.</p>	<p>1 A. Yes.</p> <p>2 Q. And so is Prolene?</p> <p>3 A. Yes.</p> <p>4 Q. And if Prolene does not have an ionic charge,</p> <p>5 then that means a material will not -- or a compound</p> <p>6 will not bind to it; correct?</p> <p>7 A. That's not necessarily so.</p> <p>8 Q. Why not?</p> <p>9 A. A lot of materials bind to other materials</p> <p>10 where there's no charge present.</p> <p>11 Q. Well, Prolene is neither acidic nor basic; is</p> <p>12 that right?</p> <p>13 A. That's correct.</p> <p>14 Q. And a dye staining to Prolene requires an</p> <p>15 acidic group or a basic group to bond with it, doesn't</p> <p>16 it?</p> <p>17 A. To bond with it.</p> <p>18 Q. To bond with it; correct?</p> <p>19 A. It might bond through some other mechanism. It</p> <p>20 might bond through a carbonyl that's been introduced by</p> <p>21 oxidation. There's some level of residual double bonds</p> <p>22 in polypropylene as an impurity, and it might add across</p> <p>23 that double bond.</p> <p>24 Q. Doctor, based on the chemistry, will oxidized</p>
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<p>1 Q. You can't answer that question one way or the</p> <p>2 other, can you?</p> <p>3 A. No.</p> <p>4 Q. Doctor, I see in your -- I see in your CV that</p> <p>5 you have an interest in charged polymers; is that</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. You're an expert on charged polymers?</p> <p>9 A. Well, we've done a fair bit of work with</p> <p>10 charged polymers.</p> <p>11 Q. You know enough about them to talk about them</p> <p>12 intelligently, don't you?</p> <p>13 A. I think so.</p> <p>14 Q. And you'll agree that polypropylene is</p> <p>15 nonionic?</p> <p>16 A. That's correct.</p> <p>17 Q. So is Prolene? Prolene is nonionic?</p> <p>18 A. Correct.</p> <p>19 Q. It doesn't have an ionic charge one way or the</p> <p>20 other; is that right?</p> <p>21 A. That's right.</p> <p>22 Q. And polypropylene is hydrophobic?</p> <p>23 A. Yes.</p> <p>24 Q. And polypropylene is pH neutral?</p>	<p>1 Prolene show any color if subjected to a staining</p> <p>2 process?</p> <p>3 A. Oxidized Prolene could very well show color.</p> <p>4 Q. How so?</p> <p>5 A. By interacting with the dye.</p> <p>6 Q. And with a chemical interaction?</p> <p>7 A. It could be physical. It could be chemical.</p> <p>8 Q. All right. Describe the chemical reaction for</p> <p>9 me, please, sir.</p> <p>10 A. There might be some functional group on the dye</p> <p>11 that might react with the carboxylic acid group.</p> <p>12 Q. Let's talk about hematoxylin. Are you familiar</p> <p>13 with hematoxylin?</p> <p>14 A. I'm really not familiar with hematoxylin.</p> <p>15 Q. Any reason to dispute it's a positive compound?</p> <p>16 A. I simply don't know one way or the other.</p> <p>17 Q. And I want you to assume for purposes of this</p> <p>18 question that hematoxylin is a positive compound. Okay?</p> <p>19 A. Positively charged?</p> <p>20 Q. Correct.</p> <p>21 A. Okay.</p> <p>22 Q. If it's positively charged, will it bind to</p> <p>23 Prolene?</p> <p>24 A. It might.</p>

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<p>1 Q. How so?</p> <p>2 A. I simply would need to know more about its</p> <p>3 structure.</p> <p>4 Q. But my question is: How so, sir?</p> <p>5 A. You know, it might just do it through</p> <p>6 hydrophobic group interactions. Hydrophobic things bind</p> <p>7 to hydrophobic things all the time.</p> <p>8 Q. Can you testify to a reasonable degree of</p> <p>9 scientific certainty whether or not hematoxylin will</p> <p>10 bind to Prolene?</p> <p>11 A. I simply don't know.</p> <p>12 Q. And, Doctor, can you testify to a reasonable</p> <p>13 degree of scientific certainty whether eosin will bind</p> <p>14 to Prolene?</p> <p>15 A. I simply don't know.</p> <p>16 Q. You will agree that there must be a chemical</p> <p>17 reaction between the dye and Prolene for there to be</p> <p>18 stain in color; correct?</p> <p>19 A. I don't think it necessarily has to be a</p> <p>20 chemical reaction. It could just be a physical</p> <p>21 phenomenon. Hydrogen bonding or something like that</p> <p>22 could do it.</p> <p>23 Q. Can you testify to that to a reasonable degree</p> <p>24 of scientific certainty?</p>	<p>1 Q. You'll agree that that's one of the best</p> <p>2 polymer science schools in the country, wouldn't you,</p> <p>3 sir?</p> <p>4 A. It's a good one. The one I did my PhD at is,</p> <p>5 arguably, number one.</p> <p>6 Q. Were you a student of Dr. Thames?</p> <p>7 A. I was not.</p> <p>8 Q. Do you know him?</p> <p>9 A. I did.</p> <p>10 Q. Do you have an opinion of him?</p> <p>11 A. Yes.</p> <p>12 Q. And what's your opinion of his polymer science</p> <p>13 expertise?</p> <p>14 A. I think he's a good paint chemist.</p> <p>15 Q. Anything else?</p> <p>16 A. That's all.</p> <p>17 Q. Do you intend to offer any opinions regarding</p> <p>18 this litigation that we've not already discussed or</p> <p>19 contained in your expert report?</p> <p>20 A. I may. My expert report contained the issues</p> <p>21 at the time I wrote it, but I may become aware of</p> <p>22 additional information. I may get samples to test. Who</p> <p>23 knows?</p> <p>24 Q. Doctor, going back to Exhibit 7, you can't</p>
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<p>1 A. Yes.</p> <p>2 Q. Have you ever attempted to stain a Prolene?</p> <p>3 A. I have not.</p> <p>4 Q. Have you ever seen Prolene hold any type of</p> <p>5 color?</p> <p>6 A. I have not.</p> <p>7 Q. Doctor, before we wrap up, I want to ask you</p> <p>8 one question. Does the pelvic region have more reactive</p> <p>9 oxygen species than the abdomen?</p> <p>10 A. I don't know.</p> <p>11 Q. And have you ever seen a study comparing the</p> <p>12 two areas of the body?</p> <p>13 A. In terms of?</p> <p>14 Q. The concentration level of reactive oxygen</p> <p>15 species.</p> <p>16 A. No.</p> <p>17 Q. Your alma mater is University of Southern</p> <p>18 Mississippi?</p> <p>19 A. Yes, I did my undergraduate studies there.</p> <p>20 Q. Proud of your education?</p> <p>21 A. Yes.</p> <p>22 Q. Did you study at the Shelby Freland Thames</p> <p>23 School of Polymer Science?</p> <p>24 A. It wasn't there when I was there.</p>	<p>1 explain why toughness increased, can you?</p> <p>2 A. I'm not convinced that toughness did increase.</p> <p>3 Q. Can you explain, Doctor, why toughness</p> <p>4 increased in Exhibit 7; yes or no?</p> <p>5 A. No, I can't.</p> <p>6 Q. Thank you. Have you understood all my</p> <p>7 questions?</p> <p>8 A. Most of them. I tried to ask for clarification</p> <p>9 when I didn't.</p> <p>10 Q. And did I give you clarification at that time?</p> <p>11 A. In most instances, yes.</p> <p>12 Q. Is there one particular question that sticks</p> <p>13 out in your mind that I asked that you simply don't</p> <p>14 understand?</p> <p>15 A. No. You kept asking about improvement of</p> <p>16 properties as a very generic, and, you know, sometimes</p> <p>17 when one property improves, another property diminishes.</p> <p>18 So I was a little confused by that, but I think we got</p> <p>19 through it.</p> <p>20 Q. That's exactly what we saw in the Burkley dog</p> <p>21 study when we look at page 183. We saw one property</p> <p>22 decrease, such as breaking strength, and one property</p> <p>23 increase, such as elongation; correct?</p> <p>24 A. That's what that page says, but I don't -- I'm</p>

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<p style="text-align: center;">Page 170</p> <p>1 unable to really evaluate that data with what I have at 2 hand. 3 MR. HUTCHINSON: I don't have any further 4 questions. Thank you for your time. Questions? 5 MR. MONSOUR: We're done. 6 MR. HUTCHINSON: Thank you. 7 (Whereupon, the deposition concluded at 8 12:17 p.m.) 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>	<p style="text-align: center;">Page 172</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 4 Please read your deposition over carefully and 5 make any necessary corrections. You should state the 6 reason in the appropriate space on the errata sheet for 7 any corrections that are made. 8 9 After doing so, please sign the errata sheet 10 and date it. It will be attached to your deposition. 11 12 It is imperative that you return the original 13 errata sheet to the deposing attorney within thirty (30) 14 days of receipt of the deposition transcript by you. If 15 you fail to do so, the deposition transcript may be 16 deemed to be accurate and may be used in court. 17 18 19 20 21 22 23 24</p>
<p style="text-align: center;">Page 171</p> <p>1 CERTIFICATE 2 3 I, JOAN L. PITTS, Registered Merit Reporter, 4 Certified Realtime Reporter, and Florida Professional 5 Reporter, do hereby certify that, pursuant to notice, 6 the deposition of JIMMY W. MAYS, PhD, was duly taken on 7 March 2, 2016, at 8:36, before me. 8 The said JIMMY W. MAYS, PhD, was duly sworn by 9 me according to law to tell the truth, the whole truth, 10 and nothing but the truth, and thereupon did testify as 11 set forth in the above transcript of testimony. The 12 testimony was taken down stenographically by me. I do 13 further certify that the above deposition is full, 14 complete, and a true record of all the testimony given 15 by the said witness. 16 17 18 JOAN L. PITTS, RMR, CRR, FPR 19 20 (The foregoing certification of this transcript 21 does not apply to any reproduction of the same by any 22 means, unless under the direct control and/or 23 supervision of the certifying reporter.) 24</p>	<p style="text-align: center;">Page 173</p> <p>1 ----- 2 ERRATA 3 ----- 4 PAGE LINE CHANGE 5 _____ 6 REASON: _____ 7 _____ 8 REASON: _____ 9 _____ 10 REASON: _____ 11 _____ 12 REASON: _____ 13 _____ 14 REASON: _____ 15 _____ 16 REASON: _____ 17 _____ 18 REASON: _____ 19 _____ 20 REASON: _____ 21 _____ 22 REASON: _____ 23 _____ 24 REASON: _____</p>

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1                   ACKNOWLEDGMENT OF DEPONENT  
2

3                   I, \_\_\_\_\_, do hereby  
4 acknowledge that I have read the foregoing pages,  
5 1 - 175, and that the same is a correct transcription of  
6 the answers given by me to the questions therein  
7 propounded, except for the corrections or changes in  
8 form or substance, if any, noted in the attached Errata  
9 Sheet.

10

11

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13                  \_\_\_\_\_  
14                  JIMMY W. MAYS, PhD              DATE

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18                  Subscribed and sworn to before me this

19                  \_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_\_.  
20                  My Commission expires: \_\_\_\_\_

21

22

23                  \_\_\_\_\_  
24                  Notary Public

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1                   LAWYER'S NOTES

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